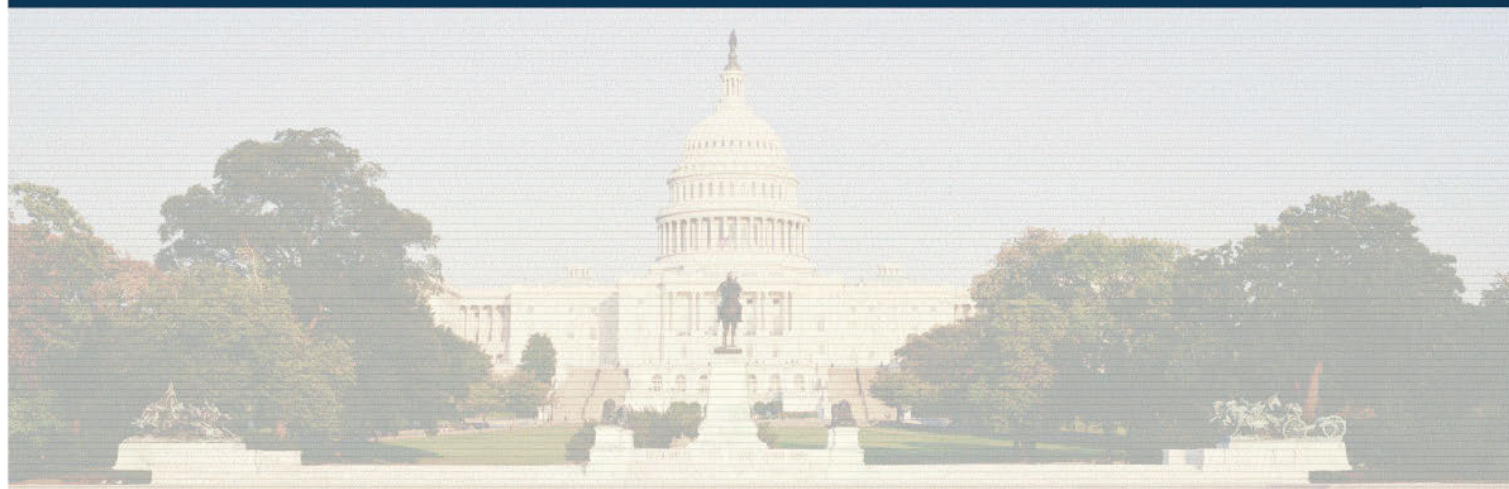


RESOURCE MANUAL:

Social Workers & Social Work Services as Defined in Medicare Law & Regulations

Citations, Analysis, & Summary



Office of Government Relations & Political Action

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INTRODUCTION

In 1965, Congress amended the Social Security Act to establish under Title XVIII the Medicare program, a federal health insurance program for people 65 years of age or older and for certain categories of disabled people. Medicare is composed of a basic hospital insurance program and a supplementary health benefits program.

The Hospital Insurance Benefits for the Aged and Disabled, Medicare Part A, offers more than hospital benefits. It provides basic coverage for inpatient hospital care and other types of institution-based inpatient care such as skilled nursing facilities and home health and hospice care. Generally, most people become entitled to the hospital insurance benefits when they reach 65 and, at the same time, become eligible for Social Security retirement, survivor benefits, or railroad retirement benefits. Others are entitled to the hospital insurance benefits due to a qualifying disability.

The Supplementary Medical Insurance Program, Medicare Part B, is a voluntary supplementary program that covers costs associated with physicians' services and other types of outpatient services not included under Part A. Although Part A is financed primarily from the Social Security tax, Part B is financed from premiums paid by enrollees, federally-appropriated funds, and specific deductible and co-payment provisions. Hospital insurance beneficiaries are automatically enrolled in the Supplementary Medical Insurance Program unless such coverage is specifically not requested.

The laws governing the basic hospital insurance benefits and the supplementary programs are contained in Parts A and B of Title XVIII of the Social Security Act. These laws are further explained in Title 42 of the Code of Federal Regulations, the federal requirements for implementing the law. Since enactment of the legislation in 1965, the law has been amended many times. There are times when proposed changes to Medicare have spurred heated political debate. This was particularly true with the Medicare Catastrophic Coverage Act of 1988, which would have expanded certain Part A and B benefits, reduced some Part A expenses, and established an upper limit on out-of-pocket expenses under Part B. But this controversial legislation was repealed in 1989. A few provisions were later reinstated, such as the additional unspecified period of coverage for hospice care services. (See the Hospice Care Services section.)

The 1997 Balanced Budget Act included the Medicare + Choice program. The law governing the Medicare + Choice program can be found in Part C of Title XVIII of the Social Security Act. Medicare + Choice allows Medicare beneficiaries to opt out of the traditional fee-for-service Medicare program into health maintenance organizations (HMOs), preferred provider organizations (PPOs), provider-sponsored organizations, and other forms of managed care.¹ There is no particular mention of social workers in the regulations related to Medicare + Choice regulations.

In 2003, Congress passed the Medicare Modernization Act (Pub. Law 108-173), which adds Part D to Title XVIII of the Social Security Act. It established a voluntary drug benefit plan for seniors regardless of income or ability to pay. It also expanded Medicare + Choice and changed its name to Medicare Advantage. Since social workers do not prescribe medications, we will not cover this law in detail.

¹ Gold, M., Achman, L., Mittler, J., and Stevens, B. (2004, August). Monitoring Medicare + Choice: What have we learned: Findings and operational lessons for Medicare Advantage. Washington, DC: Mathematica Policy Research, Inc.

This document has been designed to serve as a guide to specific sections of Medicare law and regulations that provide for both mandatory and optional provisions for social workers and social work services. The document is divided into three sections: (1) Part A benefits, (2) Part B benefits, and (3) benefits that are covered under both Parts A and B. Each section cites the provisions of law and regulations governing a specific benefit. The citations highlight the requirements related to social workers, social work services, and/or related mental health services. Every citation includes the reference to the law and regulation. This can be used as a guide if you wish to pursue a program in detail.

In some benefit areas, sections from specific Center for Medicare and Medicaid Services (CMS) instructional manuals have also been included. The manuals are documents developed by CMS to assist a provider, a state agency, a federal regional office, or a fiscal intermediary (Part A) or carrier (Part B) administering the Medicare program.

To understand Medicare law and regulations is to understand a vast body of provisions explained in various forms. What is clear is that there is little consistency in the way social workers and social work services are defined throughout Medicare law and regulations. The complexities and contradictions make it difficult for social workers to discern the conditions under which social work services are covered. This manual represents an effort to bring together the statutory and regulatory pieces that affect social workers serving Medicare clients.

Since 1987, there have been several major legislative breakthroughs that have resulted in greater coverage for clinical social work services and stronger mandatory provisions for social work services in general. With the passage of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87), clinical social workers were covered as autonomous providers in risk-sharing HMOs. That same year, the law was amended to mandate the provision of social services in skilled nursing facilities (SNFs) under Medicare and Medicaid and to require a qualified social worker in SNFs with more than 120 beds. Unfortunately, successes are sometimes short-lived. The 1997 Balanced Budget Act revoked clinical social workers' ability to bill Medicare directly for psychotherapy services rendered in the SNF setting.

The most far-reaching change came in 1989 when OBRA '89 amended the statute to provide coverage for clinical social worker services under Medicare Part B. The law went another step further in defining clinical social work services as services related to diagnosis and treatment of mental illnesses. As important as this change is, it is not without its problems related to reimbursement and clarification in terms of coverage in varying health and mental health settings.

OBRA '89 also extended coverage to clinical social workers in Medicare certified rural health clinics. Clinical psychologists were covered under OBRA '87. With the inclusion of newly designated federally qualified health centers (FQHC), first under Medicaid in 1989 followed by Medicare through OBRA '90, clinical social work services were included as one of the "core services" covered in these centers. (See the individual sections on rural health clinics and federally qualified health centers for more information.)

Despite advancements in coverage for social workers under Medicare, there are still other sections of the law that identify social services, medical social services, or social workers but neither define services covered nor qualifications needed for social workers. In some cases, there is more clarification in the regulations. For example, under hospice care, social workers are required by law to be part of an "interdisciplinary group." This body is responsible for the development and review of individual treatment plans and the establishment of policies governing the operation of the individual hospice. The regulations spell out in more detail the role of the interdisciplinary group. On the other hand, in the regulations related to the OBRA '87

changes made to partial hospitalization coverage, the regulations do not expand on the statutory language pertaining to social work or mental services, nor do they provide any guidance on specific professional qualifications.

Even where Title XVIII of the statute provides mandatory social services, there is often little teeth in the statutory language to ensure strong social work service components in local programs. For example, under the home health provisions, medical social services are provided for in the statute and are included as a condition of participation in the regulations, which means the individual home health agency is required to provide such services with salaried personnel or through an arrangement with another agency. Yet, medical social services can only be covered if a physician orders the use of such services and includes it as part of a plan of treatment. Consequently, the active use of medical social services in a home health agency or in other Medicare programs, such as inpatient hospital services, hospice, or comprehensive outpatient rehabilitation facility services, will vary depending on the individual agency or provider and their commitment to make medical social services or social work services an integral part of a total treatment plan.

We hope this manual is useful in serving as a guide to how the labyrinth of Medicare laws and regulations define social workers and social work services.

Laws and regulations continually change. This document is current as of the date of publication.

A GUIDE TO USING THIS MANUAL

This manual contains information on 13 Medicare benefits. Each section includes a brief narrative describing the covered services for the individual benefit program area, with particular attention to the social work-related services, the appropriate statutory and regulatory citations, and in some cases, citations from Center for Medicare and Medicaid Services policy manuals.

Statutory excerpts have a heading that says “Social Security Act § #####.” Regulatory excerpts have a heading that starts as Part ###. Excerpts from the Medicare Policy Manuals have a heading that starts with Chapter #.

All citations have been **bolded** to highlight those sections of the law that specifically address social workers, social services, or other related issues. Other sections of the law included in this manual are important to social workers, but do not relate directly to social workers or social work services.

The use of a series of dots (.....) indicates that the passages cited are only excerpts from the law, regulations, or policy manuals.

In 2001, the Health Care Financing Administration (HCFA) was renamed the Center for Medicare and Medicaid Services (CMS). Some laws have been updated with the new name of the agency; others have not. Throughout this document, HCFA and CMS are used interchangeably, but the current name of the agency is CMS.

MEDICARE PART A
(Hospital Insurance Benefits for the Aged and Disabled)

INPATIENT HOSPITAL SERVICES – MEDICAL SOCIAL SERVICES

The Social Security Act provides Medicare coverage for medical social services when they are ordinarily furnished by a hospital for the care and treatment of inpatients. Neither the law nor the regulations define the qualifications of a social worker, nor what medical social services in a hospital setting entail.

The *Medicare Hospital Manual*, however, offers CMS's definition of medical social services with respect to meeting a patient's medically-related social needs.

“Medical social services are those social services which contribute meaningfully to the treatment of a patient's condition. Such services include, but are not limited to, (a) assessment of the social and emotional factors related to the patient's illness, his need for care, his response to treatment, and his adjustment to care in the hospital; (b) appropriate action to obtain case work services to assist in resolving problems in these areas; (c) assessment of the patient's medical and nursing requirements, his home situation, his financial resources, and the community resources available to him in making the decision regarding his discharge.”²

The regulations do state that a condition of participation in the Medicare program is that hospitals “must have an ongoing plan, consistent with available community and hospital resources, to provide or make available social work, psychological and educational services to meet the medically-related needs of its patients.”³ As with all in-patient hospital services provided over time, social services must be certified by a physician as part of an individual's medical treatment.

With the enactment of the Omnibus Budget Reconciliation Act of 1986 (OBRA '86), Congress required that hospitals, as a condition of participation, have a discharge planning process for patients entitled to Medicare benefits to facilitate the provision of follow-up care. The regulations require discharge planning for Medicare patients "who are likely to suffer adverse health consequences upon discharge if there is no adequate discharge planning." The discharge planning evaluation process will be extended to other patients on request.⁴

According to the statute and regulation, a registered nurse, social worker, or "other appropriately qualified personnel" is responsible for the evaluation process and developing or supervising the development of the discharge plan. Again, qualifications for social workers or "other appropriately qualified personnel" are not included in the law or regulations.

² U.S. Department of Health and Human Services. (2001). *Medicare Hospital Manual* [Online]. Retrieved from http://www.cms.hhs.gov/manuals/pm_trans/R776HO.pdf

³ Conditions of Participation for Hospitals, 42 C.F.R. 482.21 (2003).

⁴ Conditions of Participation for Hospitals, 42 C.F.R. 482.43 (2003).

Rehabilitative services on an in-hospital basis can also be covered where it requires a relatively intense rehabilitation program involving a multidisciplinary team of skilled personnel to enable a patient to function on an independent level. A team might include skilled rehabilitation nursing care, physical therapy, occupational therapy, and possibly speech therapy and prosthetic-orthotic services. Mental health and social services are also covered to enable a patient to progress more effectively.⁵

⁵ 1990 Medicare Explained. (1990). Chicago: Commerce Clearing House, Inc.

SOCIAL SECURITY ACT § 1814

42USC1395f

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part A--Hospital Insurance Benefits for Aged and Disabled

Sec. 1395f. Conditions of and limitations on payment for services

(a) Requirement of requests and certifications

Except as provided in subsections (d) and (g) of this section and in section 1395mm of this title, payment for services furnished an individual may be made only to providers of services which are eligible therefore under section 1395cc of this title and only if—

.....

(3) with respect to inpatient hospital services (other than inpatient psychiatric hospital services) which are furnished over a period of time, a physician certifies that such services are required to be given on an inpatient basis for such individual's medical treatment, or that inpatient diagnostic study is medically required and such services are necessary for such purpose, except that (A) such certification shall be furnished only in such cases, with such frequency, and accompanied by such supporting material, appropriate to the cases involved, as may be provided by regulations, and (B) the first such certification required in accordance with clause (A) shall be furnished no later than the 20th day of such period;

(4) in the case of inpatient psychiatric hospital services, the services are those which the records of the hospital indicate were furnished to the individual during periods when he was receiving (A) intensive treatment services, (B) admission and related services necessary for a diagnostic study, or (C) equivalent services;

.....

SOCIAL SECURITY ACT § 1861

42USC1395x

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part D--Miscellaneous Provisions

(b) Inpatient hospital services

The term "inpatient hospital services" means the following items and services furnished to an inpatient of a hospital and (except as provided in paragraph (3)) by the hospital--

(1) bed and board;

(2) such nursing services and other related services, such use of hospital facilities, and such **medical social services** as are ordinarily furnished by the hospital for the care and treatment of inpatients, and such drugs, biologicals, supplies, appliances, and equipment, for use in the hospital, as are ordinarily furnished by such hospital for the care and treatment of inpatients; and

(3) such other diagnostic or therapeutic items or services, furnished by the hospital or by others under arrangements with them made by the hospital, as are ordinarily furnished to inpatients either by such hospital or by others under such arrangements; excluding, however--

(4) medical or surgical services provided by a physician, resident, or intern, services described by subsection (s)(2)(K) of this section, certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist; and

(5) the services of a private-duty nurse or other private-duty attendant.

.....

(e) Hospital

The term ``hospital" (except for purposes of sections 1395f(d), 1395f(f), and 1395n(b) of this title, subsection (a)(2) of this section, paragraph (7) of this subsection, and subsection (i) of this section) means an institution which--

(1) is primarily engaged in providing, by or under the supervision of physicians, to inpatients (A) diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or (B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons;

(2) maintains clinical records on all patients;

(3) has bylaws in effect with respect to its staff of physicians;

(4) has a requirement that every patient with respect to whom payment may be made under this subchapter must be under the care of a physician, except that a patient receiving qualified psychologist services (as defined in subsection (ii) of this section) may be under the care of a clinical psychologist with respect to such services to the extent permitted under State law;

.....,

(6)(A) has in effect a hospital utilization review plan which meets the requirements of subsection (k) of this section and (B) has in place a discharge planning process that meets the requirements of subsection (ee) of this section;

..... _

(ee) Discharge planning process -

(1) A discharge planning process of a hospital shall be considered sufficient if it is applicable to services furnished by the hospital to individuals entitled to benefits under this subchapter and if it meets the guidelines and standards established by the Secretary under paragraph (2).

(2) The Secretary shall develop guidelines and standards for the discharge planning process in order to ensure a timely and smooth transition to the most appropriate type of and setting for post-hospital or rehabilitative care. The guidelines and standards shall include the following:

(A) The hospital must identify, at an early stage of hospitalization, those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning.

(B) Hospitals must provide a discharge planning evaluation for patients identified under subparagraph (A) and for other patients upon the request of the patient, patient's representative, or patient's physician.

(C) Any discharge planning evaluation must be made on a timely basis to ensure that appropriate arrangements for post-hospital care will be made before discharge and to avoid unnecessary delays in discharge.

(D) A discharge planning evaluation must include an evaluation of a patient's likely need for appropriate post-hospital services, including hospice services, and the availability of those services, including the availability of home health services through individuals and entities that participate in the program under this subchapter and that serve the area in which the patient resides and that request to be listed by the hospital as available.

(E) The discharge planning evaluation must be included in the patient's medical record for use in establishing an appropriate discharge plan and the results of the evaluation must be discussed with the patient (or the patient's representative).

(F) Upon the request of a patient's physician, the hospital must arrange for the development and initial implementation of a discharge plan for the patient.

(G) Any discharge planning evaluation or discharge plan required under this paragraph must be developed by, or under the supervision of, a registered professional nurse, **social worker**, or other appropriately qualified personnel.

(H) Consistent with section 1395a of this title, the discharge plan shall--

(i) not specify or otherwise limit the qualified provider which may provide post-hospital home health services, and

(ii) identify (in a form and manner specified by the Secretary) any entity to whom the individual is referred in which the hospital has a disclosable financial interest (as specified by the Secretary consistent with section 1395cc(a)(1)(S) of this title) or which has such an interest in the hospital.

(3) With respect to a discharge plan for an individual who is enrolled with a Medicare+Choice organization under a Medicare+Choice plan and is furnished inpatient hospital services by a hospital under a contract with the organization--

(A) the discharge planning evaluation under paragraph (2)(D) is not required to include information on the availability of home health services through individuals and entities which do not have a contract with the organization; and

(B) notwithstanding subparagraph (H)(i) \10\, the plan may specify or limit the provider (or providers) of post-hospital home health services or other post-hospital services under the plan.

.....

PART 409--HOSPITAL INSURANCE BENEFITS

Subpart B—Inpatient Hospital Services and Inpatient Critical Access Hospital Services

§ 409.10 Included services.

(a) Subject to the conditions, limitations, and exceptions set forth in this subpart, the term “inpatient hospital or inpatient CAH services” means the following services furnished to an inpatient of a participating hospital or of a participating CAH or, in the case of emergency services or services in foreign hospitals, to an inpatient of a qualified hospital:

- (1) Bed and board.
 - (2) Nursing services and other related services.
 - (3) Use of hospital or CAH facilities.
 - (4) **Medical social services.**
 - (5) Drugs, biologicals, supplies, appliances, and equipment.
 - (6) Certain other diagnostic or therapeutic services.
 - (7) Medical or surgical services provided by certain interns or residents-in-training.
 - (8) Transportation services, including transport by ambulance.
- (b) *Inpatient hospital services* does not include the following types of services:
- (1) Posthospital SNF care, as described in § 409.20, furnished by a hospital or a critical access hospital that has a swing-bed approval.
 - (2) Nursing facility services, described in § 440.155 of this chapter, that may be furnished as a Medicaid service under title XIX of the Act in a swingbed hospital that has an approval to furnish nursing facility services.
 - (3) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(4) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(5) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(6) Certified nurse mid-wife services, as defined in section 1861(gg) of the Act.

(7) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(8) Services of an anesthetist, as defined in § 410.69

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985; 58 FR 30666, May 26, 1993; 64 FR 3648, Jan. 25, 1999; 65 FR 18535, Apr. 7, 2000]

.....

§ 409.12 Nursing and related services, medical social services; use of hospital or CAH facilities.

(a) Except as provided in paragraph (b) of this section, Medicare pays for nursing and related services, use of hospital or CAH facilities, **and medical social services** as inpatient hospital or inpatient CAH services only if those services are ordinarily furnished by the hospital or CAH, respectively, for the care and treatment of inpatients.

(b) *Exception.* Medicare does not pay for the services of a private duty nurse or attendant. An individual is not considered to be a private duty nurse or attendant if he or she is a hospital or CAH employee at the time the services are furnished.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985; 58 FR 30666, 30667, May 26, 1993]

PART 482--CONDITIONS OF PARTICIPATION FOR HOSPITALS

Subpart C—Basic Hospital Functions

§ 482.21 Condition of participation: Quality assurance.

The governing body must ensure that there is an effective, hospital-wide quality assurance program to evaluate the provision of patient care.

(a) *Standard: Clinical plan.* The organized, hospital-wide quality assurance program must be ongoing and have a written plan of implementation.

(1) All organized services related to patient care, including services furnished by a contractor, must be evaluated.

(2) Nosocomial infections and medication therapy must be evaluated.

(3) All medical and surgical services performed in the hospital must be evaluated as they relate to appropriateness of diagnosis and treatment.

(b) *Standard: Medically-related patient care services.* The hospital must have an ongoing plan, consistent with available community and hospital resources, to provide or make available **social work**, psychological, and educational services to meet the medically-related needs of its patients.

(c) *Standard: Implementation.* The hospital must take and document appropriate remedial action to address deficiencies found through the quality assurance program. The hospital must document the outcome of the remedial action. [51 FR 22042, June 17, 1986, as amended at 59 FR 64152, Dec. 13, 1994]

.....

§ 482.43 Condition of participation: Discharge planning.

The hospital must have in effect a discharge planning process that applies to all patients. The hospital's policies and procedures must be specified in writing.

(a) *Standard: Identification of patients in need of discharge planning.* The hospital must identify at an early stage of hospitalization all patients who are likely to suffer adverse health consequences upon discharge if there is no adequate discharge planning.

(b) *Standard: Discharge planning evaluation.*

(1) The hospital must provide a discharge planning evaluation to the patients identified in paragraph (a) of this section, and to other patients upon the patient's request, the request of a person acting on the patient's behalf, or the request of the physician.

(2) A registered nurse, **social worker**, or other appropriately qualified personnel must develop, or supervise the development of, the evaluation.

(3) The discharge planning evaluation must include an evaluation of the likelihood of a patient needing post-hospital services and of the availability of the services.

(4) The discharge planning evaluation must include an evaluation of the likelihood of a patient's capacity for selfcare or of the possibility of the patient being cared for in the environment from which he or she entered the hospital.

(5) The hospital personnel must complete the evaluation on a timely basis so that appropriate arrangements for post-hospital care are made before discharge, and to avoid unnecessary delays in discharge.

(6) The hospital must include the discharge planning evaluation in the patient's medical record for use in establishing an appropriate discharge plan and must discuss the results of the evaluation with the patient or individual acting on his or her behalf.

(c) *Standard: Discharge plan.* (1) A registered nurse, **social worker**, or other appropriately qualified personnel must develop, or supervise the development of, a discharge plan if the discharge planning

evaluation indicates a need for a discharge plan.

(2) In the absence of a finding by the hospital that a patient needs a discharge plan, the patient's physician may request a discharge plan. In such a case, the hospital must develop a discharge plan for the patient.

(3) The hospital must arrange for the initial implementation of the patient's discharge plan.

(4) The hospital must reassess the patient's discharge plan if there are factors that may affect continuing care needs or the appropriateness of the discharge plan.

(5) As needed, the patient and family members or interested persons must be counseled to prepare them for post-hospital care.

(d) *Standard: Transfer or referral.* The hospital must transfer or refer patients, along with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed, for followup or ancillary care.

(e) *Standard: Reassessment.* The hospital must reassess its discharge planning process on an on-going basis. The reassessment must include a review of discharge plans to ensure that they are responsive to discharge needs.

[59 FR 64152, Dec. 13, 1994]

PSYCHIATRIC HOSPITAL SERVICES – SOCIAL SERVICES/SOCIAL WORKER

Psychiatric services are covered either as an acute care program within a general hospital or as provided by a psychiatric hospital. The 190-day lifetime limitation on payment applies only to inpatient psychiatric hospital services. There is no limit on services in an acute care unit within a regular participating hospital.

In addition to the same requirements of a regular hospital, a participating psychiatric hospital must also meet additional regulatory requirements that relate to specialized staffing and medical records. Psychiatric hospitals are required to have a social services department with a director that either has a master's degree in social work (MSW) or experience and education in social services for mentally ill people. If the director does not have an MSW, at least one staff member must have one.

Social services, as with all services in a psychiatric hospital, can be covered only for active treatment that can reasonably be expected to improve the patient's condition. The regulations identify discharge planning, arranging for follow-up care, and developing mechanisms for information exchange with other services as some of the responsibilities of the social services staff. Additionally, the *Medicare Hospital Manual* also identifies social workers as one of several qualified professionals under the direction of a physician who may be included as part of a therapeutic team providing active treatment. The related citations from the *Medicare Hospital Manual* have been included.

Social work services on an outpatient basis are covered services. Because such outpatient services are funded under the Part B supplementary benefits program, the requirements are discussed in the Outpatient Mental Health Services and Partial Hospitalization sections.

SOCIAL SECURITY ACT § 1812

42USC1395d

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part A--Hospital Insurance Benefits for Aged and Disabled

Sec. 1395d. Scope of benefits

...

(c) Inpatients of psychiatric hospitals

If an individual is an inpatient of a psychiatric hospital on the first day of the first month for which he is entitled to benefits under this part, the days on which he was an inpatient of such a hospital in the 150-day period immediately before such first day shall be included in determining the number of days limit under subsection (b)(1) of this section insofar as such limit applies to (1) inpatient psychiatric hospital services, or (2) inpatient hospital services for an individual who is an inpatient primarily for the diagnosis or treatment of mental illness (but shall not be included in determining such number of days limit insofar as it applies to other inpatient hospital services or in determining the 190-day limit under subsection (b)(3) of this section).

SOCIAL SECURITY ACT § 1814

42USC1395f

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part A--Hospital Insurance Benefits for Aged and Disabled

Sec. 1395f. Conditions of and limitations on payment for services

(a) Requirement of requests and certifications

Except as provided in subsections (d) and (g) of this section and in section 1395mm of this title, payment for services furnished an individual may be made only to providers of services which are eligible therefore under section 1395cc of this title and only if—

.....

(2) a physician, or, in the case of services described in subparagraph (B), a physician, or a nurse practitioner or clinical nurse specialist who does not have a direct or indirect employment relationship with the facility but is working in collaboration with a physician, certifies (and recertifies, where such services are furnished over a period of time, in such cases, with such frequency, and accompanied by such supporting material, appropriate to the case involved, as may be provided by regulations, except that the first of such recertifications shall be required in each case of inpatient hospital services not later than the 20th day of such period) that--

(A) in the case of inpatient psychiatric hospital services, such services are or were required to be given on an inpatient basis, by or under the supervision of a physician, for the

psychiatric treatment of an individual; and (i) such treatment can or could reasonably be expected to improve the condition for which such treatment is or was necessary or (ii) inpatient diagnostic study is or was medically required and such services are or were necessary for such purposes;

...

(4) in the case of inpatient psychiatric hospital services, the services are those which the records of the hospital indicate were furnished to the individual during periods when he was receiving (A) intensive treatment services, (B) admission and related services necessary for a diagnostic study, or (C) equivalent services;

SOCIAL SECURITY ACT § 1861

42USC1395x

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part D--Miscellaneous Provisions

(b) Inpatient hospital services

The term ``inpatient hospital services" means the following items and services furnished to an inpatient of a hospital and (except as provided in paragraph (3)) by the hospital--

(1) bed and board;

(2) such nursing services and other related services, such use of hospital facilities, and such **medical social services** as are ordinarily furnished by the hospital for the care and treatment of inpatients, and such drugs, biologicals, supplies, appliances, and equipment, for use in the hospital, as are ordinarily furnished by such hospital for the care and treatment of inpatients; and

(3) such other diagnostic or therapeutic items or services, furnished by the hospital or by others under arrangements with them made by the hospital, as are ordinarily furnished to inpatients either by such hospital or by others under such arrangements; excluding, however--

(4) medical or surgical services provided by a physician, resident, or intern, services described by subsection (s)(2)(K) of this section, certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist; and

(5) the services of a private-duty nurse or other private-duty attendant.

...

(c) Inpatient psychiatric hospital services

The term ``inpatient psychiatric hospital services" means inpatient hospital services furnished to an inpatient of a psychiatric hospital.

(d) Repealed. Pub. L. 98-369, div. B, title III, Sec. 2335(b)(1), July 18, 1984, 98 Stat. 1090

(e) Hospital

The term ``hospital" (except for purposes of sections 1395f(d), 1395f(f), and 1395n(b) of this title, subsection (a)(2) of this section, paragraph (7) of this subsection, and subsection (i) of this section) means an institution which--

(1) is primarily engaged in providing, by or under the supervision of physicians, to inpatients (A) diagnostic services and therapeutic services for medical diagnosis, treatment,

and care of injured, disabled, or sick persons, or (B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons;

(2) maintains clinical records on all patients;

(3) has bylaws in effect with respect to its staff of physicians;

(4) has a requirement that every patient with respect to whom payment may be made under this subchapter must be under the care of a physician, except that a patient receiving qualified psychologist services (as defined in subsection (ii) of this section) may be under the care of a clinical psychologist with respect to such services to the extent permitted under State law;

...

(6)(A) has in effect a hospital utilization review plan which meets the requirements of subsection (k) of this section and (B) has in place a discharge planning process that meets the requirements of subsection (ee) of this section;

.....

(f) Psychiatric hospital

The term ``psychiatric hospital" means an institution which--

(1) is primarily engaged in providing, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons;

(2) satisfies the requirements of paragraphs (3) through (9) of subsection (e) of this section;

(3) maintains clinical records on all patients and maintains such records as the Secretary finds to be necessary to determine the degree and intensity of the treatment provided to individuals entitled to hospital insurance benefits under part A of this subchapter; and

(4) meets such staffing requirements as the Secretary finds necessary for the institution to carry out an active program of treatment for individuals who are furnished services in the institution.

In the case of an institution which satisfies paragraphs (1) and (2) of the preceding sentence and which contains a distinct part which also satisfies paragraphs (3) and (4) of such sentence, such distinct part shall be considered to be a ``psychiatric hospital".

...

(ee) Discharge planning process

(1) A discharge planning process of a hospital shall be considered sufficient if it is applicable to services furnished by the hospital to individuals entitled to benefits under this subchapter and if it meets the guidelines and standards established by the Secretary under paragraph (2).

(2) The Secretary shall develop guidelines and standards for the discharge planning process in order to ensure a timely and smooth transition to the most appropriate type of and setting for post-hospital or rehabilitative care. The guidelines and standards shall include the following:

(A) The hospital must identify, at an early stage of hospitalization, those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning.

(B) Hospitals must provide a discharge planning evaluation for patients identified under subparagraph (A) and for other patients upon the request of the patient, patient's representative, or patient's physician.

(C) Any discharge planning evaluation must be made on a timely basis to ensure that appropriate arrangements for post-hospital care will be made before discharge and to avoid unnecessary delays in discharge.

(D) A discharge planning evaluation must include an evaluation of a patient's likely need for appropriate post-hospital services, including hospice services, and the availability of those services, including the availability of home health services through individuals and entities that participate in the program under this subchapter and that serve the area in which the patient resides and that request to be listed by the hospital as available.

(E) The discharge planning evaluation must be included in the patient's medical record for use in establishing an appropriate discharge plan and the results of the evaluation must be discussed with the patient (or the patient's representative).

(F) Upon the request of a patient's physician, the hospital must arrange for the development and initial implementation of a discharge plan for the patient.

(G) Any discharge planning evaluation or discharge plan required under this paragraph must be developed by, or under the supervision of, a registered professional nurse, **social worker**, or other appropriately qualified personnel.

(H) Consistent with section 1395a of this title, the discharge plan shall--

(i) not specify or otherwise limit the qualified provider which may provide post-hospital home health services, and

(ii) identify (in a form and manner specified by the Secretary) any entity to whom the individual is referred in which the hospital has a disclosable financial interest (as specified by the Secretary consistent with section 1395cc(a)(1)(S) of this title) or which has such an interest in the hospital.

(3) With respect to a discharge plan for an individual who is enrolled with a Medicare+Choice organization under a Medicare+Choice plan and is furnished inpatient hospital services by a hospital under a contract with the organization--

(A) the discharge planning evaluation under paragraph (2)(D) is not required to include information on the availability of home health services through individuals and entities which do not have a contract with the organization; and

(B) notwithstanding subparagraph (H)(i) \10\, the plan may specify or limit the provider (or providers) of post-hospital home health services or other post-hospital services under the plan.

PART 482--CONDITIONS OF PARTICIPATION FOR HOSPITALS

Subpart E—Requirements for Specialty Hospitals

§ 482.60 Special provisions applying to psychiatric hospitals.

Psychiatric hospital must—

(a) Be primarily engaged in providing, by or under the supervision of a doctor of medicine or osteopathy, psychiatric services for the diagnosis and treatment of mentally ill persons;

§ 482.61 Condition of participation: Special medical record requirements for psychiatric hospitals.

The medical records maintained by a psychiatric hospital must permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the institution.

(a) *Standard: Development of assessment/diagnostic data.* Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the patient is hospitalized.

(1) The identification data must include the patient's legal status.

(2) A provisional or admitting diagnosis must be made on every patient at the time of admission, and must include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses.

(3) The reasons for admission must be clearly documented as stated by the patient and/or others significantly involved.

(4) The **social service records**, including reports of interviews with patients, family members, and others, must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history.

(5) When indicated, a complete neurological examination must be recorded at the time of the admission physical examination.

(b) *Standard: Psychiatric evaluation.*

Each patient must receive a psychiatric evaluation that must—

(1) Be completed within 60 hours of admission;

(2) Include a medical history;

(3) Contain a record of mental status;

(4) Note the onset of illness and the circumstances leading to admission;

(5) Describe attitudes and behavior;

(6) Estimate intellectual functioning, memory functioning, and orientation; and

(7) Include an inventory of the patient's assets in descriptive, not interpretative, fashion.

(c) *Standard: Treatment plan.* (1) Each patient must have an individual comprehensive treatment plan that must be based on an inventory of the patient's strengths and disabilities. The written plan must include—

(i) A substantiated diagnosis;

(ii) Short-term and long-range goals;

(iii) The specific treatment modalities utilized;

(iv) The responsibilities of each member of the treatment team; and

(v) Adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out.

(2) The treatment received by the patient must be documented in such a way to assure that all active therapeutic efforts are included.

(d) *Standard: Recording progress.*

Progress notes must be recorded by the doctor of medicine or osteopathy responsible for the care of the patient as specified in § 482.12(c), nurse, **social worker** and, when appropriate, others significantly involved in active treatment modalities. The frequency of progress notes is determined by the condition of the patient but must be recorded at least weekly for the first 2 months and at least once a month thereafter and must contain

recommendations for revisions in the treatment plan as indicated as well as precise assessment of the patient's progress in accordance with the original or revised treatment plan.

(e) *Standard: Discharge planning and discharge summary.* The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the patient's hospitalization and recommendations from appropriate services concerning follow-up or aftercare as well as a brief summary of the patient's condition on discharge.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

§ 482.62 Condition of participation: Special staff requirements for psychiatric hospitals.

The hospital must have adequate numbers of qualified professional and supportive staff to evaluate patients, formulate written, individualized comprehensive treatment plans, provide active treatment measures, and engage in discharge planning.

(a) *Standard: Personnel.* The hospital must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to:

- (1) Evaluate patients;
- (2) Formulate written individualized, comprehensive treatment plans;
- (3) Provide active treatment measures; and
- (4) Engage in discharge planning.

(b) *Standard: Director of inpatient psychiatric services; medical staff.* Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program. The number and qualifications of doctors of medicine and osteopathy must be adequate to provide essential psychiatric services.

(1) The clinical director, service chief, or equivalent must meet the training and experience requirements for examination by

the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry.

(2) The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.

(c) *Standard: Availability of medical personnel.* Doctors of medicine or osteopathy

and other appropriate professional personnel must be available to provide necessary medical and surgical diagnostic and treatment services. If medical and surgical diagnostic and treatment services are not available within the institution, the institution must have an agreement with an outside source of these services to ensure that they are immediately available or a satisfactory agreement must be established for transferring patients to a general hospital that participates in the Medicare program.

(d) *Standard: Nursing services.* The hospital must have a qualified director of psychiatric nursing services. In addition to the director of nursing, there must be adequate numbers of registered nurses, licensed practical nurses, and **mental health workers** to provide nursing care necessary under each patient's active treatment program and to maintain progress notes on each patient.

(1) The director of psychiatric nursing services must be a registered nurse who has a master's degree in psychiatric or mental health nursing, or its equivalent from a school of nursing accredited by the National League for Nursing, or be qualified by education and experience in the care of the mentally ill. The director must demonstrate competence to participate in interdisciplinary formulation of individual treatment plans; to give skilled nursing care and therapy; and to

direct, monitor, and evaluate the nursing care furnished.

(2) The staffing pattern must insure the availability of a registered professional nurse 24 hours each day. There must be adequate numbers of registered nurses, licensed practical nurses, **and mental health workers** to provide the nursing care necessary under each patient's active treatment program.

(e) *Standard: Psychological services.*

The hospital must provide or have available psychological services to meet the needs of the patients.

(f) *Standard: Social services.* There must be a **director of social services** who monitors and evaluates the quality and appropriateness of social services furnished. The services must be furnished in accordance with accepted standards of practice and established policies and procedures.

(1) The director of the social work department or service must have a **master's degree from an accredited school of social work** or must be qualified by education and experience in the social services needs of the mentally ill. If the

director does not hold a **masters degree in social work**, at least one staff member must have this qualification.

(2) **Social service staff responsibilities** must include, but are not limited to, participating in discharge planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate information with sources outside the hospital.

(g) *Standard: Therapeutic activities.*

The hospital must provide a therapeutic activities program.

(1) The program must be appropriate to the needs and interests of patients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.

(2) The number of qualified therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each patient's active treatment program.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

Medicare Benefit Policy Manual

CHAPTER 2 - INPATIENT PSYCHIATRIC HOSPITAL SERVICES

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10 - Covered Inpatient Psychiatric Hospital Services

(Rev. 1, 10-01-03)

A3-3102, HO-212

Patients covered under hospital insurance are entitled to have payment made for inpatient hospital services furnished to them while an inpatient of a psychiatric hospital. See the Medicare Benefit Policy Manual, Chapter 4, "Inpatient Psychiatric Benefit Days Reduction and Lifetime Limitation," §50 for the 190-day lifetime limitation on payment for inpatient psychiatric hospital services and the Medicare Benefit Policy Manual, Chapter 4, "Inpatient Psychiatric Benefit Days Reduction and Lifetime Limitation," §§10 - 50, for the pre-entitlement inpatient psychiatric benefit days reduction provision.

20 - Active Treatment in Psychiatric Hospitals

(Rev. 1, 10-01-03)

A3-3102.1, HO-212.1

The term "inpatient psychiatric hospital services" means inpatient hospital services furnished to an inpatient of a psychiatric hospital. Payment for inpatient psychiatric hospital services is to be made only for "active treatment" that can reasonably be expected to improve the patient's condition. To assure that payment is made only under such circumstances, the law includes certain requirements that must be met before the services furnished in a psychiatric hospital can be covered.

First, the certification that a physician must provide with respect to inpatient psychiatric hospital services is required to include a statement that the services furnished can reasonably be expected to improve the patient's condition. See Pub.100-1, Medicare General Information, Eligibility and Entitlement Manual, Chapter 4, §10.9, for certification requirements.

Second, the law provides that payment may be made for these services only if they were being furnished while the patient was receiving either active treatment or admission and related services necessary for diagnostic study. In the context of inpatient psychiatric hospital services, emphasis is placed on the presence of "active treatment" and, therefore, this determination is the crucial one. Simply applying the skilled care definition for general

hospitals is not sufficient for determining whether payment may be made since that definition does not take into account the patient's potential for improvement nor was it designed to permit the more sophisticated judgments required by the concept of active treatment.

20.1 - Definition of Active Treatment

(Rev. 1, 10-01-03)

A3-3102.1.A, HO-212.1.A

For services in a psychiatric hospital to be designated as "active treatment," they must be:

- Provided under an individualized treatment or diagnostic plan;
- Reasonably expected to improve the patient's condition or for the purpose of diagnosis; and
- Supervised and evaluated by a physician.

Such factors as diagnosis, length of hospitalization, and the degree of functional limitation, while useful as general indicators of the kind of care most likely being furnished in a given situation, are not controlling in deciding whether the care was active treatment. Refer to [42 CFR 482.61](#) on "Conditions of Participation for Hospitals" for a full description of what constitutes active treatment.

20.1.1 - Individualized Treatment or Diagnostic Plan

(Rev. 1, 10-01-03)

A3-3102.1.A.1, HO-212.1.A.1

The services must be provided in accordance with an individualized program of treatment or diagnosis developed by a physician in conjunction with staff members of appropriate other disciplines on the basis of a thorough evaluation of the patient's restorative needs and potentialities. Thus, an isolated service, (e.g., a single session with a psychiatrist, or a routine laboratory test) not furnished under a planned program of therapy or diagnosis would not constitute active treatment, even though the service was therapeutic or diagnostic in nature. The plan of treatment must be recorded in the patient's medical record in accordance with [42 CFR 482.61](#) on "Conditions of Participation for Hospitals."

20.1.2 - Services Expected to Improve the Condition or for Purpose of Diagnosis

(Rev. 1, 10-01-03)

A3-3102.1.A.2, HO-212.1.A.2

The services must reasonably be expected to improve the patient's condition or must be for the purpose of diagnostic study. It is not necessary that a course of therapy have as its goal the restoration of the patient to a level which would permit discharge from the institution although the treatment must, at a minimum, be designed both to reduce or control the patient's psychotic or neurotic symptoms that necessitated hospitalization and improve the patient's level of functioning.

The types of services which meet the above requirements would include not only psychotherapy, drug therapy, and shock therapy, but also such adjunctive therapies as occupational therapy, recreational therapy, and milieu therapy, provided the adjunctive therapeutic services are expected to result in improvement (as defined above) in the patient's condition. If the only activities prescribed for the patient are primarily diversional in nature, (i.e., to provide some social or recreational outlet for the patient), it would not be regarded as treatment to improve the patient's condition. In many large hospitals these adjunctive services are present and part of the life experience of every patient. In a case where milieu therapy (or one of the other adjunctive therapies) is involved, it is particularly important that this therapy be a planned program for the particular patient and not one where life in the hospital is designated as milieu therapy.

In accordance with the above definition of "improvement," the administration of antidepressant or tranquilizing drugs which are expected to significantly alleviate a patient's psychotic or neurotic symptoms would be termed active treatment (assuming that the other elements of the definitions are met). However, the administration of a drug or drugs does not of itself necessarily constitute active treatment. Thus, the use of mild tranquilizers or sedatives solely for the purpose of relieving anxiety or insomnia would not constitute active treatment.

30 - Services Supervised and Evaluated by a Physician (Rev. 1, 10-01-03)

A3-3102.1.A.3, HO-212.1.A.3

Physician participation in the services is an essential ingredient of active treatment. The services of qualified individuals other than physicians, e.g., **social workers**, occupational therapists, group therapists, attendants, etc., must be prescribed and directed by a physician to meet the specific psychiatric needs of the individual. In short, the physician must serve as a source of information and guidance for all members of the therapeutic team who work directly with the patient in various roles. It is the responsibility of the physician to periodically evaluate the therapeutic program and determine the extent to which treatment goals are being realized and whether changes in direction or emphasis are needed. Such evaluation should be made on the basis of periodic consultations and conferences with therapists, reviews of the patient's medical record, and regularly scheduled patient interviews, at least once per week.

Although in an institutional setting the services of a physician may be readily available, the general pattern is for the physician to visit the patient only periodically, delegating to nursing personnel the responsibility for intensive observation of patients, where it is necessary. Such periodic visits to a patient do not in themselves constitute active treatment. Conversely, when the physician periodically evaluates the therapeutic program to determine the extent to which treatment goals are being realized and whether changes in direction or emphasis are needed (based on consultations and conferences with therapists, review of the patient's progress as recorded on the medical record and the physician's periodic conversations with

the patient), active treatment would be indicated. The treatment furnished the patient should be documented in the medical record in such a manner and with such frequency as to provide a full picture of the therapy administered as well as an assessment of the patient's reaction to it. (See [42 CFR 482.61\(c\)](#) and [42 CFR 482.61\(d\)](#) on Conditions of Participation).

A finding that a patient is not receiving active treatment will not in itself preclude payment for physicians' services under Part B. As long as the professional services rendered by the physician are reasonable and necessary for the care of the patient, such services would be reimbursable under the medical insurance program.

30.1 - Principles for Evaluating a Period of Active Treatment (Rev. 1, 10-01-03)

A3-3102.1.B, HO-212.1.B

The period of time covered by the physician's certification is referred to a "period of active treatment." This period should include all days on which inpatient psychiatric hospital services were provided because of the individual's need for active treatment (not just the days on which specific therapeutic or diagnostic services are rendered). For example, a patient's program of treatment may necessitate the discontinuance of therapy for a period of time or it may include a period of observation, either in preparation for or as a follow-up to therapy, while only maintenance or protective services are furnished. If such periods were essential to the overall treatment plan, they would be regarded as part of the period of "active treatment."

The fact that a patient is under the supervision of a physician does not necessarily mean the patient is getting active treatment. For example, medical supervision of a patient may be necessary to assure the early detection of significant changes in his/her condition; however, in the absence of a specific program of therapy designed to effect improvement, a finding that the patient is receiving active treatment would be precluded.

The program's definition of active treatment does not automatically exclude from coverage services rendered to patients who have conditions that ordinarily result in progressive physical and/or mental deterioration. Although patients with such diagnosis will most commonly be receiving custodial care, they may also receive services that meet the program's definition of "active treatment" (e.g., where a patient with Alzheimer's disease or Pick's disease received services designed to alleviate the effects of paralysis, epileptic seizures, or some other neurological symptom, or where a patient in the terminal stages of any disease received life-supportive care). A period of hospitalization during which services of this kind were furnished would be regarded as a period of "active treatment."

40 - Definition of Nonpsychiatric Care in Psychiatric Hospital (Rev. 1, 10-01-03)

A3-3102.2, HO-212.2

Nonpsychiatric care in a psychiatric hospital is care for a medical condition not related to mental health care. It includes medical or surgery care for diagnoses that are not related to

mental health. Inpatient hospital services are covered where a patient receives medical or surgical care in a psychiatric hospital, but does not satisfy the requirements dealing with active psychiatric treatment (see §20 above) if:

- The medical or surgical service requires a hospital level of care;
- Hospitalization in a psychiatric institution, rather than a general hospital, is appropriate because of some factor related to the patient's mental condition; and
- A physician certifies that these conditions are met.

The patient's past history of psychiatric problems or the possibility that he/she has a current psychiatric condition could furnish a proper base for the exercise of medical judgment in concluding that admission to psychiatric hospital is "medically necessary."

CHAPTER 4 - INPATIENT PSYCHIATRIC BENEFIT DAYS REDUCTION AND LIFETIME LIMITATION

10 - Inpatient Psychiatric Benefit Days Reduction

(Rev. 1, 10-01-03)

A3-3104, HO-217

If an individual is in a participating psychiatric hospital on the first day of the entitlement to hospital insurance, the number of inpatient benefit days in the first benefit period is subject to reduction. The days (not necessarily consecutive) on which an individual was an inpatient of a psychiatric hospital in the 150-day period immediately before the first day of entitlement must be subtracted from the 150 days of inpatient hospital services for which he/she would otherwise be eligible in the first benefit period. Days spent in a general hospital for diagnosis or treatment of a psychiatric condition prior to entitlement will not reduce the patient's 150 inpatient benefit days in the initial benefit period.

After entitlement, the reduction applies not only to inpatient hospital services received in a psychiatric hospital, but also to services received in a general hospital if the individual is an inpatient of the general hospital primarily for the diagnosis or treatment of mental illness. If a patient has no psychiatric benefit days remaining because of the reduction, Medicare payment may still be made for up to 150 days of inpatient hospital services that are not for the diagnosis and treatment of mental illness.

EXAMPLE 1

John was admitted to a Medicare participating psychiatric hospital named Spring Psychiatric Hospital on January 20. John's Medicare entitlement was effective February 1 while John was still an inpatient of Spring Psychiatric Hospital. The 12 days of inpatient psychiatric

care prior to entitlement are deducted from the 150 days available in the first benefit period. John has 138 days available in the first benefit period (150 minus 12 = 138).

EXAMPLE 2

Mary was admitted to Spring Psychiatric Hospital on January 2 and discharged January 31. She was readmitted March 1 and discharged April 15. Mary's Medicare entitlement became effective April 1. Mary used a total of 60 psychiatric days in the 150 day period prior to her Medicare entitlement. Therefore, the days available to Mary in her first benefit period are 90 days. Pre-entitlement days used by Mary were 29 for her January admission and 31 used during her March admission prior to her entitlement April 1.

10.1 - Patient Status on Day of Entitlement

(Rev. 1, 10-01-03)

A3-3104.1, HO-217.1

A patient in a participating psychiatric hospital on the first day of entitlement is subject to this reduction. The reduction applies to patients admitted to or discharged from such a hospital on their first day of entitlement, or who begin or end a leave of absence on that day. Where only a distinct part of an institution is participating as a psychiatric hospital, the provision applies only to patients who, on their first day of entitlement, are inpatients of that part.

10.2 - Institution's Status in Determining Days Deducted

(Rev. 1, 10-01-03)

A3-3104.2, HO-217.2

The status of a psychiatric hospital (or a distinct part of such a hospital) as of the individual's first day of entitlement is controlling in determining whether days spent there during the preceding 150 days are to be deducted. Thus, deductions would be made for days spent in a hospital (or distinct part) that was participating as of the individual's first day of entitlement even though it was not participating during all or part of the preceding 150 days. However, where an institution is not participating as of the individual's first day of entitlement, deductions would not be made for days spent in that institution during the preceding 150 days, even though the institution is later certified for participation as a psychiatric hospital.

Where a participating psychiatric hospital is a distinct part of an institution, deductions are made only for days spent in the wards, floors, wings, etc., included in the participating distinct part as of the individual's first day of entitlement, even though it was not participating during all or part of the preceding 150 days. Deductions are not made for days spent in a part of the institution not included in the participating distinct part as of the individual's first day of entitlement, e.g., days spent in a custodial section of the institution or days spent in a general medical-surgical facility participating as a general hospital.

EXAMPLE 1

Alice was admitted to Spring Psychiatric Hospital which is a participating hospital on January 2 and discharged January 31. She was admitted to General Mental Health Hospital which is not a Medicare participating hospital on March 1 through March 30. On March 31, Alice was admitted to Spring Psychiatric Hospital. Alice's Medicare became effective April 1. The pre-entitlement days deducted from Mary's first benefit period are those used during her stay in Spring Psychiatric Hospital which is a Medicare participating hospital. The pre-entitlement days used are 29 in January and 1 in March for a total of 30. Therefore, Alice has 120 days remaining in her first benefit period.

20 - Days of Admission, Discharge, and Leave

(Rev. 1, 10-01-03)

See the Medicare Benefit Policy Manual, Chapter 3, Duration of Covered Inpatient Services, for counting Medicare admission, discharge, and leave of absence days.

30 - Reduction for Psychiatric Services in General Hospitals

(Rev. 1, 10-01-03)

A3-3104.4, HO-217.4

When an individual subject to a reduction in days is an inpatient in a general hospital the intermediary will apply the reduction only if it has determined that the individual was an inpatient primarily for the diagnosis or treatment of mental illness.

The intermediary normally will make a decision based on the principle diagnosis shown on the claim. The reduction will not be applied where the principle diagnosis is not related to mental illness, even though other diagnoses may relate to mental illness.

If the intermediary needs more information than the principle diagnosis to make the required determination, it should obtain it from the hospital, the attending physician, or other appropriate source. Any case in which a reasonable question persists about whether the individual was an inpatient "primarily for the diagnosis or treatment of mental illness" should be resolved in favor of not applying the reduction.

The term "mental illness" is defined as the specific psychiatric conditions described in the "American Psychiatric Association's Diagnostic and Statistical Manual – Mental Disorders."

40 - Determining Days Available

(Rev. 1, 10-01-03)

A3-3104.5, HO-217.5, 42 CFR 409.63

Since payment can be made only for the number of days remaining after the reduction is applied, the following steps should be taken to determine the number of days available in the first benefit period for which payment can be made for inpatient psychiatric hospital services and inpatient services in a general hospital for the treatment of mental illness:

1. Determine how many days in the 150-day pre-entitlement period the patient spent in a psychiatric hospital;
2. Subtract these from 150.

Payment is made for the remaining days in the following order of priority:

1. The 60 full benefit days;
2. The 30 regular coinsurance days;
3. The 60 lifetime reserve coinsurance days.

Benefit days not available to the patient because of the psychiatric reduction (including lifetime reserve days) nevertheless, remain available for use in hospitalization not subject to the reduction; i.e., a general hospital stay for a nonpsychiatric condition. The lifetime days not previously used also remain available for any inpatient stays (including psychiatric hospital stays) in subsequent benefit periods.

EXAMPLE 1

The patient was an inpatient of a participating psychiatric hospital on his first day of entitlement. He had been in such a hospital in the pre-entitlement period for 20 days. Therefore, 130 days are payable. Payment would be made in the following order: 60 full benefit days, 30 coinsurance (61st thru 90th) days, then 40 coinsurance (lifetime) days.

EXAMPLE 2

During the 150-day period preceding Medicare entitlement, an individual had been a patient of a general hospital for 60 days of inpatient psychiatric care and had spent 90 days in a psychiatric hospital, ending with the first day of entitlement. During the initial benefit period, the beneficiary spent 90 days in a general hospital and received psychiatric care there. The 60 days spent in the general hospital for psychiatric treatment before entitlement does not reduce the benefits available in the first benefit period. Only the 90 days spent in the psychiatric hospital before entitlement reduce such benefits, leaving a total of 60 available psychiatric days. However, after entitlement, the reduction applies not only to days spent in a psychiatric hospital, but also to days of psychiatric treatment in a general hospital. Thus, Medicare payment could be made only for 60 of the 90 days spent in the general hospital.

EXAMPLE 3

An individual was admitted to a general hospital for a mental condition and, after 10 days, transferred to a participating psychiatric hospital. The individual remained in the psychiatric hospital for 78 days before becoming entitled to hospital insurance benefits and for 130 days after entitlement. The beneficiary was then transferred to a general hospital and received treatment of a medical condition for 20 days. The 10 days spent in the general hospital during

the 150-day preentitlement period have no effect on the inpatient hospital benefit days available to the individual for psychiatric care in the first benefit period, even though the general hospital stay was for a mental condition. Only the 78 days spent in the psychiatric hospital during the pre-entitlement period are subtracted from the 150 benefit days. Accordingly, the individual has 72 days of psychiatric care (150 days less 78 days) available in the first benefit period. Benefits could be paid for the individual's hospitalization during the first benefit period in the following manner. For the 130-day psychiatric hospital stay, 72 days (60 full benefit days and 12 coinsurance days), and for the general hospital stay, 20 days (18 coinsurance and 2 lifetime reserve days).

50 - Inpatient Psychiatric Hospital Services - Lifetime Limitation
(Rev. 1, 10-01-03)

A3-3105, HO-218

Payment may not be made for more than a total of 190 days of inpatient psychiatric hospital services during the patient's lifetime. The limitation applies only to services furnished in a psychiatric hospital. The period spent in a psychiatric hospital prior to entitlement does not count against the patient's lifetime limitation, even though preentitlement days may have been counted against the 150 days of eligibility in the first benefit period.

The CWF keeps track of days paid for inpatient psychiatric services and informs the intermediary on claims where the 190-day limit is reached.

CHAPTER 5 - LIFETIME RESERVE DAYS

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.....
10 - Summary of Provision

(Rev. 1, 10-01-03)

A3-3106.A, HO-219.A

Each beneficiary has a lifetime reserve of 60 days of inpatient hospital services to draw upon after having used 90 days of inpatient hospital services in a benefit period. Payment will be made for such additional days of hospital care after the 90 days of benefits have been exhausted unless the individual elects not to have such payment made (and thus saves the reserve days for a later time).

A coinsurance amount equal to one-half of the inpatient hospital deductible applies to lifetime reserve days.

10.1 - Effect of Reserve Days on Guarantee of Payment Provision

(Rev. 1, 10-01-03)

A3-3106.B, HO-219.B, A3-3714

The guarantee of payment provisions extend to inpatient services furnished to individuals who have exhausted their eligibility for inpatient hospital services and does not extend to individuals who have no coverage for other reasons, e.g., one who is not entitled under hospital insurance or whose entitlement has been terminated.

Under the guarantee of payment provisions a hospital may be paid, under certain conditions, for inpatient services furnished to a beneficiary whose eligibility for inpatient benefit days has been exhausted, including exhaustion of the 190-day lifetime limitation on inpatient psychiatric hospital services. The guarantee of payment provisions are not applicable until the individual has exhausted 60 lifetime reserve days of inpatient hospital services except where the beneficiary is deemed to have elected not to use lifetime reserve days. (See §10.2, below, and see §30, below.)

See the Medicare Claim Processing Manual, Chapter 2 for instructions relating to guarantee of payment.

10.2 - Reserve Days Not Available Where Average Charges Do Not Exceed One-Half Inpatient Hospital Deductible

(Rev. 1, 10-01-03)

A3-3106.C, HO-219.C

A beneficiary will be deemed to have elected not to use the lifetime reserve days where the average daily charge for covered services furnished during a lifetime reserve days billing period is equal to or less than the coinsurance amount for the lifetime reserve days. Such days are treated as noncovered days rather than potential lifetime reserve days since the beneficiary would be required to pay for all of the hospital charges regardless of his or her election and therefore would not benefit from use of lifetime reserve days. This rule applies to hospitals not paid under PPS. See §30 for deemed election under PPS.

10.3 - Availability of Reserve Days Where Psychiatric Limitations Are Involved

(Rev. 1, 10-01-03)

A3-3106.D, HO-219.D

A beneficiary's reserve days are not available to the extent that he or she is subject to the 150-day psychiatric hospital reduction provision, i.e., where the beneficiary has been in a psychiatric hospital during the 150-day period immediately preceding the first day of entitlement to hospital insurance benefits and is still in a psychiatric hospital on the first day of entitlement. (See the Medicare Benefit Policy Manual, Chapter 4, §10.) The reserve days are available, however, if such a beneficiary receives nonpsychiatric services in a general hospital or if the beneficiary starts a new benefit period. The reserve days are also not available to a beneficiary who is in a psychiatric hospital after using 190 days of inpatient psychiatric hospital care during his or her lifetime. (See the Medicare Benefit Policy Manual, Chapter 4, §50.)

10.4 - Availability of Reserve Days for Hospital Emergency Services

(Rev. 1, 10-01-03)

A3-3106.E, HO-219.E

The reserve days are available for emergency services furnished in nonparticipating hospitals.

10.5 - Physician Certification

(Rev. 1, 10-01-03)

A3-3106.F, HO-219.F

Physician certification requirements are applicable to lifetime reserve days.

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SKILLED NURSING FACILITY – SOCIAL SERVICES/SOCIAL WORKER

Skilled nursing facility services, which also are referred to as extended care services, can be better understood as nursing home care for individuals requiring skilled medical or nursing care on a daily basis or skilled rehabilitation services for the rehabilitation of injured, disabled, or sick people. A skilled nursing facility (SNF) is an institution or a distinct part of an institution that has a transfer agreement with one or more participating hospitals and is not primarily responsible for the care and treatment of mental diseases.

Medicare Part A covers post-hospital extended care services in a qualified SNF for up to 100 days in any one "spell of illness." "A spell of illness, also popularly called a 'benefit period,' is a period of consecutive days that begins with the first day (not included in a previous spell of illness) on which a patient is furnished inpatient hospital or extended care services by a 'qualified' provider in a month for which the patient is entitled to Part A benefits."⁶ A qualified provider can be a hospital (including a psychiatric hospital) or a skilled nursing facility. Skilled nursing facility services are only covered after a patient has been transferred to a SNF from a hospital where the person was a patient for not less than three consecutive days. The transfer to a SNF can include an admission to the SNF within 30 days from the day of discharge from the hospital. There are certain circumstances under which a patient can be admitted to a SNF more than 30 days following hospital discharge.

As a result of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87), major changes were made in the Medicare and Medicaid statutory provisions governing SNFs and intermediate care facilities under Medicaid. The Health Care Financing Administration (HCFA) issued the final rule with a comment period for the new nursing home reform requirements in the February 2, 1989 issue of the *Federal Register*. Because of the many comments received, HCFA delayed implementation of the regulations until October 1, 1990. Significant changes in the requirements for social work are summarized below.

OBRA '87 revised the requirements for nursing homes (including those related to quality of care, the provision of services, residents' rights, and administration), the process of monitoring compliance with the law, and the remedies available to federal and state agencies in the event of noncompliance. The requirements related to the provision of services that are of greatest significance to social workers are as follows:

- *Quality of life.* The nursing facility must promote the maintenance or enhancement of a patient's quality of life and maintain a quality assessment and assurance committee (composed of the nursing director, a physician, and three other facility staff members), which meets at least quarterly to identify necessary quality assurance activities and implement plans to correct deficiencies.
- *Plan of care.* Services must be provided according to a plan of care, initially developed by a team, which describes the medical, nursing, and psychosocial needs of residents and how these needs will be met. The plan is to be reviewed and revised periodically following the resident assessment.
- *Resident assessment.* A comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity must be conducted or coordinated by a registered nurse no later than four days following admission. The assessment

⁶ 1990 Medicare Explained. (1990). Chicago: Commerce Clearing House, Inc.

must, among other things, describe the resident's capabilities and significant impairments in performing daily life functions. Each of the professionals participating in the assessment must sign and certify that portion of the assessment for which they are responsible under threat of civil monetary penalties of \$1,000 to \$5,000 per assessment for falsification.

- *Provision of services and activities.* The skilled nursing facility must provide or arrange for all necessary services including medically-related social services, which meet professional standards of quality. Qualified professionals must provide all services according to written plans of care (U.S. Department of Health and Human Services (DHHS), 1998, pp. 117-118).⁷

The statutory requirements related to social services mandate that such services be provided to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident. In addition, a skilled nursing facility with more than 120 beds must employ at least one full-time qualified social worker. The law defines a social worker as one who has a bachelor's degree in social work or similar professional qualifications. The final regulation was more specific in defining a qualified social worker as an individual with a bachelor's degree in social work or in a human services field including, but not limited to, sociology, special education, rehabilitation counseling, and psychology. In addition, the social worker must have one year of supervised social work experience in a health care setting working directly with individuals.

In a technical amendment to the Medicare Catastrophic Coverage Act of 1988 (Conference Report cited below), the conferees instructed the Secretary of the U.S. Department of Health and Human Services to ensure that regulations "regarding consultation and supervision of social work services be at least as stringent as those in effect prior to enactment of these changes." The final rule failed to include qualification standards that are as stringent as those previously in effect. The earlier regulations (42 CFR 405.1101 and 405.1130) were superseded by the new regulations. These older regulations defined a qualified social worker in the following manner:

Social worker (qualified consultant). A person who is licensed, if applicable, by the State in which practicing, is a graduate of a school of social work accredited or approved by the Council on Social Work Education, and has 1 year of social work experience in a health care setting. (42 CFR 405.1101)

Furthermore, the regulation previously in effect required as a condition of participation that If the facility offers social services, a member of the staff of the facility is designated as responsible for social services. If the designated person is not a qualified social worker, the facility has a written agreement with a qualified social worker or recognized social agency for consultation and assistance on a regularly scheduled basis. (42 CFR 405.1130)

In OBRA '90, amendment language was included that directed the U.S. Department of Health and Human Services to develop regulations mandating that requirements applicable to providers be as strict as those prior to OBRA '87 (see citation). While the final rule did strengthen the qualification standards for social workers, the language nonetheless falls short of what was previously required by regulation. Furthermore, the final rule continues to remain silent on the issue of consultation and supervision of social work services and social service staffing requirements for nursing facilities under 120 beds.

⁷ U.S. Department of Health and Human Services. (1998). HCFA Legislative Summary - Omnibus Reconciliation Act of 1987, P.L. 100-203. Washington, DC: U.S. Government Printing Office.

The regulations delete the use of Level A and Level B designations in identifying nursing facility requirements. Social services were designated as a Level B requirement. HCFA has previously stated that both Level A and Level B designations were to be enforced equally in terms of nursing facility requirements. With the new regulations, this is no longer an issue. However, the use of Level A and Level B requirements will continue for survey purposes until, according to HCFA, enforcement procedures and forms can be changed.

Additionally, skilled nursing facilities must permit reasonable access from social service providers to residents provided the resident wants the service.

SOCIAL SECURITY ACT § 1814

42USC1395f

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part A--Hospital Insurance Benefits for Aged and Disabled

Sec. 1395f. Conditions of and limitations on payment for services

.....

(2) a physician, or, in the case of services described in subparagraph (B), a physician, or a nurse practitioner or clinical nurse specialist who does not have a direct or indirect employment relationship with the facility but is working in collaboration with a physician, certifies (and recertifies, where such services are furnished over a period of time, in such cases, with such frequency, and accompanied by such supporting material, appropriate to the case involved, as may be provided by regulations, except that the first of such recertifications shall be required in each case of inpatient hospital services not later than the 20th day of such period) that--

(A) in the case of inpatient psychiatric hospital services, such services are or were required to be given on an inpatient basis, by or under the supervision of a physician, for the psychiatric treatment of an individual; and (i) such treatment can or could reasonably be expected to improve the condition for which such treatment is or was necessary or (ii) inpatient diagnostic study is or was medically required and such services are or were necessary for such purposes;

(B) in the case of post-hospital extended care services, such services are or were required to be given because the individual needs or needed on a daily basis skilled nursing care (provided directly by or requiring the supervision of skilled nursing personnel) or other skilled rehabilitation services, which as a practical matter can only be provided in a skilled nursing facility on an inpatient basis, for any of the conditions with respect to which he was receiving inpatient hospital services (or services which would constitute inpatient hospital services if the institution met the requirements of paragraphs (6) and (9) of section 1395x(e) of this title) prior to transfer to the skilled nursing facility or for a condition requiring such extended care services which arose after such transfer and while he was still in the facility for treatment of the condition or conditions for which he was receiving such inpatient hospital services;

.....

SOCIAL SECURITY ACT § 1861

42USC1395x

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part D--Miscellaneous Provisions

(h) Extended care services

The term ``extended care services" means the following items and services furnished to an inpatient of a skilled nursing facility and (except as provided in paragraphs (3), (6), and (7)) by such skilled nursing facility--

(1) nursing care provided by or under the supervision of a registered professional nurse;
(2) bed and board in connection with the furnishing of such nursing care;
(3) physical or occupational therapy or speech-language pathology services furnished by the skilled nursing facility or by others under arrangements with them made by the facility;

(4) **medical social services;**

(5) such drugs, biologicals, supplies, appliances, and equipment, furnished for use in the skilled nursing facility, as are ordinarily furnished by such facility for the care and treatment of inpatients;

(6) medical services provided by an intern or resident-in-training of a hospital with which the facility has in effect a transfer agreement (meeting the requirements of subsection (l) of this section), under a teaching program of such hospital approved as provided in the last sentence of subsection (b) of this section, and other diagnostic or therapeutic services provided by a hospital with which the facility has such an agreement in effect; and

(7) such other services necessary to the health of the patients as are generally provided by skilled nursing facilities, or by others under arrangements with them made by the facility; excluding, however, any item or service if it would not be included under subsection (b) of this section if furnished to an inpatient of a hospital.

(i) Post-hospital extended care services

The term ``post-hospital extended care services" means extended care services furnished an individual after transfer from a hospital in which he was an inpatient for not less than 3 consecutive days before his discharge from the hospital in connection with such transfer. For purposes of the preceding sentence, items and services shall be deemed to have been furnished to an individual after transfer from a hospital, and he shall be deemed to have been an inpatient in the hospital immediately before transfer therefrom, if he is admitted to the skilled nursing facility (A) within 30 days after discharge from such hospital, or (B) within such time as it would be medically appropriate to begin an active course of treatment, in the case of an individual whose condition is such that skilled nursing facility care would not be medically appropriate within 30 days after discharge from a hospital; and an individual shall be deemed not to have been discharged from a skilled nursing facility if, within 30 days after discharge therefrom, he is admitted to such facility or any other skilled nursing facility.

(j) Skilled nursing facility

The term ``skilled nursing facility" has the meaning given such term in section 1395i-3(a) of this title.

SOCIAL SECURITY ACT § 1819

42USC1395i-3

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part A--Hospital Insurance Benefits for Aged and Disabled

Sec. 1395i-3. Requirements for, and assuring quality of care in, skilled nursing facilities

(a) ``Skilled nursing facility" defined

In this subchapter, the term ``skilled nursing facility" means an institution (or a distinct part of an institution) which--

(1) is primarily engaged in providing to residents--

(A) skilled nursing care and related services for residents who require medical or nursing care, or

(B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons, and is not primarily for the care and treatment of mental diseases;

(2) has in effect a transfer agreement (meeting the requirements of section 1395x(l) of this title) with one or more hospitals having agreements in effect under section 1395cc of this title; and

(3) meets the requirements for a skilled nursing facility described in subsections (b), (c), and (d) of this section.

(b) Requirements relating to provision of services

(1) Quality of life

(A) In general

A skilled nursing facility must care for its residents in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life of each resident.

(B) Quality assessment and assurance

A skilled nursing facility must maintain a quality assessment and assurance committee, consisting of the director of nursing services, a physician designated by the facility, and at least 3 other members of the facility's staff, which (i) meets at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary and (ii) develops and implements appropriate plans of action to correct identified quality deficiencies. A State or the Secretary may not require disclosure of the records of such committee except insofar as such disclosure is related to the compliance of such committee with the requirements of this subparagraph.

(2) Scope of services and activities under plan of care

A skilled nursing facility must provide services to attain or maintain the highest practicable physical, mental, and **psychosocial well-being** of each resident, in accordance with a written plan of care which--

(A) describes the medical, nursing, and psychosocial needs of the resident and how such needs will be met;

(B) is initially prepared, with the participation to the extent practicable of the resident or the resident's family or legal representative, by a team which includes the resident's attending physician and a registered professional nurse with responsibility for the resident; and

(C) is periodically reviewed and revised by such team after each assessment under paragraph (3).

(3) Residents' assessment

(A) Requirement

A skilled nursing facility must conduct a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity, which assessment--

- (i) describes the resident's capability to perform daily life functions and significant impairments in functional capacity;
- (ii) is based on a uniform minimum data set specified by the Secretary under subsection (f)(6)(A) of this section;
- (iii) uses an instrument which is specified by the State under subsection (e)(5) of this section; and
- (iv) includes the identification of medical problems.

(B) Certification

(i) In general

Each such assessment must be conducted or coordinated (with the appropriate participation of health professionals) by a registered professional nurse who signs and certifies the completion of the assessment. Each individual who completes a portion of such an assessment shall sign and certify as to the accuracy of that portion of the assessment.

(ii) Penalty for falsification

(I) An individual who willfully and knowingly certifies under clause (i) a material and false statement in a resident assessment is subject to a civil money penalty of not more than \$1,000 with respect to each assessment.

(II) An individual who willfully and knowingly causes another individual to certify under clause (i) a material and false statement in a resident assessment is subject to a civil money penalty of not more than \$5,000 with respect to each assessment.

(III) The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under this clause in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(iii) Use of independent assessors

If a State determines, under a survey under subsection (g) of this section or otherwise, that there has been a knowing and willful certification of false assessments under this paragraph, the State may require (for a period specified by the State) that resident assessments under this paragraph be conducted and certified by individuals who are independent of the facility and who are approved by the State.

(C) Frequency

(i) In general

Subject to the timeframes prescribed by the Secretary under section 1395yy(e)(6) of this title, such an assessment must be conducted--

(I) promptly upon (but no later than 14 days after the date of) admission for each individual admitted on or after October 1, 1990, and by not later than January 1, 1991, for each resident of the facility on that date;

(II) promptly after a significant change in the resident's physical or mental condition; and

(III) in no case less often than once every 12 months.

(ii) Resident review

The skilled nursing facility must examine each resident no less frequently than once every 3 months and, as appropriate, revise the resident's assessment to assure the continuing accuracy of the assessment.

(D) Use

The results of such an assessment shall be used in developing, reviewing, and revising the resident's plan of care under paragraph (2).

(E) Coordination

Such assessments shall be coordinated with any State-required preadmission screening program to the maximum extent practicable in order to avoid duplicative testing and effort.

(4) Provision of services and activities

(A) In general

To the extent needed to fulfill all plans of care described in paragraph (2), a skilled nursing facility must provide, directly or under arrangements (or, with respect to dental services, under agreements) with others for the provision of--

- (i) nursing services and specialized rehabilitative services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident;
 - (ii) medically-related **social services** to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident;
 - (iii) pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident;
 - (iv) dietary services that assure that the meals meet the daily nutritional and special dietary needs of each resident;
 - (v) an on-going program, directed by a qualified professional, of activities designed to meet the interests and the physical, mental, and psychosocial well-being of each resident;
 - (vi) routine and emergency dental services to meet the needs of each resident;
- and
- (vii) treatment and services required by mentally ill and mentally retarded residents not otherwise provided or arranged for (or required to be provided or arranged for) by the State.

The services provided or arranged by the facility must meet professional standards of quality. Nothing in clause (vi) shall be construed as requiring a facility to provide or arrange for dental services described in that clause without additional charge.

.....,

(G) ``Licensed health professional" defined

In this paragraph, the term ``licensed health professional" means a physician, physician assistant, nurse practitioner, physical, speech, or occupational therapist, physical or occupational therapy assistant, registered professional nurse, licensed practical nurse, **licensed or certified social worker**, registered respiratory therapist, or certified respiratory therapy technician.

(6) Physician supervision and clinical records

A skilled nursing facility must--

(A) require that the medical care of every resident be provided under the supervision of a physician;

(B) provide for having a physician available to furnish necessary medical care in case of emergency; and

(C) maintain clinical records on all residents, which records include the plans of care (described in paragraph (2)) and the residents' assessments (described in paragraph (3)).

(7) **Required social services**

In the case of a skilled nursing facility with more than 120 beds, the facility must have at least one **social worker (with at least a bachelor's degree in social work or similar professional qualifications)** employed full-time to provide or assure the provision of social services.

.....
(3) Access and visitation rights

A skilled nursing facility must--

(A) permit immediate access to any resident by any representative of the Secretary, by any representative of the State, by an ombudsman described in paragraph (2)(B)(iii)(II), or by the resident's individual physician;

(B) permit immediate access to a resident, subject to the resident's right to deny or withdraw consent at any time, by immediate family or other relatives of the resident;

(C) permit immediate access to a resident, subject to reasonable restrictions and the resident's right to deny or withdraw consent at any time, by others who are visiting with the consent of the resident;

(D) permit reasonable access to a resident by any entity or individual that provides health, **social**, legal, or other services to the resident, subject to the resident's right to deny or withdraw consent at any time; and

(E) permit representatives of the State ombudsman (described in paragraph (2)(B)(iii)(II)), with the permission of the resident (or the resident's legal representative) and consistent with State law, to examine a resident's clinical records.

(4) Equal access to quality care

A skilled nursing facility must establish and maintain identical policies and practices regarding transfer, discharge, and covered services under this subchapter for all individuals regardless of source of payment.

.....
(d) Requirements relating to administration and other matters

(1) Administration

(A) In general

A skilled nursing facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical \4\ **mental, and psychosocial well-being** of each resident (consistent with requirements established under subsection (f)(5) of this section).

\\4\\ So in original. Probably should be followed by a comma.

.....
(g) Survey and certification process

(1) State and Federal responsibility

(A) In general

Pursuant to an agreement under section 1395aa of this title, each State shall be responsible for certifying, in accordance with surveys conducted under paragraph (2), the compliance of skilled nursing facilities (other than facilities of the State) with the requirements of subsections (b), (c), and (d) of this section. The Secretary shall be responsible for certifying, in accordance with surveys conducted under paragraph (2), the compliance of State skilled nursing facilities with the requirements of such subsections.

(B) Educational program

Each State shall conduct periodic educational programs for the staff and residents (and their representatives) of skilled nursing facilities in order to present current regulations, procedures, and policies under this section.

(C) Investigation of allegations of resident neglect and abuse and misappropriation of resident property

The State shall provide, through the agency responsible for surveys and certification of nursing facilities under this subsection, for a process for the receipt and timely review and investigation of allegations of neglect and abuse and misappropriation of resident property by a nurse aide of a resident in a nursing facility or by another individual used by the facility in providing services to such a resident. The State shall, after providing the individual involved with a written notice of the allegations (including a statement of the availability of a hearing for the individual to rebut the allegations) and the opportunity for a hearing on the record, make a written finding as to the accuracy of the allegations. If the State finds that a nurse aide has neglected or abused a resident or misappropriated resident property in a facility, the State shall notify the nurse aide and the registry of such finding. If the State finds that any other individual used by the facility has neglected or abused a resident or misappropriated resident property in a facility, the State shall notify the appropriate licensure authority. A State shall not make a finding that an individual has neglected a resident if the individual demonstrates that such neglect was caused by factors beyond the control of the individual.

(D) Removal of name from nurse aide registry

(i) In general

In the case of a finding of neglect under subparagraph (C), the State shall establish a procedure to permit a nurse aide to petition the State to have his or her name removed from the registry upon a determination by the State that—

(I) the employment and personal history of the nurse aide does not reflect a pattern of abusive behavior or neglect; and

(II) the neglect involved in the original finding was a singular occurrence.

(ii) Timing of determination

In no case shall a determination on a petition submitted under clause (i) be made prior to the expiration of the 1-year period beginning on the date on which the name of the petitioner was added to the registry under subparagraph (C).

(E) Construction

The failure of the Secretary to issue regulations to carry out this subsection shall not relieve a State of its responsibility under this subsection.

(2) Surveys

(A) Standard survey

(i) In general

Each skilled nursing facility shall be subject to a standard survey, to be conducted without any prior notice to the facility. Any individual who notifies (or causes to be notified) a skilled nursing facility of the time or date on which such a survey is scheduled to be conducted is subject to a civil money penalty of not to exceed \$2,000. The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title. The Secretary shall review each State's procedures for the scheduling and conduct of standard surveys to assure that the State has taken all reasonable steps to avoid giving notice of such a survey through the scheduling procedures and the conduct of the surveys themselves.

(ii) Contents

Each standard survey shall include, for a case-mix stratified sample of residents--

(I) a survey of the quality of care furnished, as measured by indicators of medical, nursing, and rehabilitative care, dietary and nutrition services, activities and social participation, and sanitation, infection control, and the physical environment,

(II) written plans of care provided under subsection (b)(2) of this section and an audit of the residents' assessments under subsection (b)(3) of this section to determine the accuracy of such assessments and the adequacy of such plans of care, and

(III) a review of compliance with residents' rights under subsection (c) of this section.

(iii) Frequency

(I) In general

Each skilled nursing facility shall be subject to a standard survey not later than 15 months after the date of the previous standard survey conducted under this subparagraph. The Statewide average interval between standard surveys of skilled nursing facilities under this subsection shall not exceed 12 months.

(II) Special surveys

If not otherwise conducted under subclause (I), a standard survey (or an abbreviated standard survey) may be conducted within 2 months of any change of ownership, administration, management of a skilled nursing facility, or the director of nursing in order to determine whether the change has resulted in any decline in the quality of care furnished in the facility.

SOCIAL SECURITY ACT § 1883

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part D--Miscellaneous Provisions

Sec. 1395tt. Hospital providers of extended care services

(a) Hospital facility agreements; reasonable costs of services

(1) Any hospital which has an agreement under section 1395cc of this title may (subject to subsection (b) of this section) enter into an agreement with the Secretary under which its inpatient hospital facilities may be used for the furnishing of services of the type which, if furnished by a skilled nursing facility, would constitute extended care services.

(2)(A) Notwithstanding any other provision of this subchapter, payment to any hospital for services furnished under an agreement entered into under this section shall be based upon the reasonable cost of the services as determined under subparagraph (B).

(B)(i) The reasonable cost of the services consists of the reasonable cost of routine services (determined under clause (ii)) and the reasonable cost of ancillary services (determined under clause (iii)).

(ii) The reasonable cost of routine services furnished during any calendar year by a hospital under an agreement under this section is equal to the product of--

(I) the number of patient-days during the year for which the services were furnished, and

(II) the average reasonable cost per patient-day, such average reasonable cost per patient-day being the average rate per patient-day paid for routine services during the most recent year for which cost reporting data are available with respect to such services (increased in a compounded manner by the applicable increase for payments for routine service costs of skilled nursing facilities under subsections (a) through (d) of section 1395yy of this title for subsequent cost reporting periods and up to and including such calendar year) under this subchapter to freestanding skilled nursing facilities in the region (as defined in section 1395ww(d)(2)(D) of this title) in which the facility is located.

(iii) The reasonable cost of ancillary services shall be determined in the same manner as the reasonable cost of ancillary services provided for inpatient hospital services.

(b) Eligible facilities

The Secretary may not enter into an agreement under this section with any hospital unless, except as provided under subsection (g) of this section, the hospital is located in a rural area and has less than 100 beds.

(c) Terms and conditions of facility agreements

An agreement with a hospital under this section shall, except as otherwise provided under regulations of the Secretary, be of the same duration and subject to termination on the same conditions as are agreements with skilled nursing facilities under section 1395cc of this title and shall, where not inconsistent with any provision of this section, impose the same duties, responsibilities, conditions, and limitations, as those imposed under such agreements entered into under section 1395cc of this title; except that no such agreement with any hospital shall be in effect for any period during which the hospital does not have in effect an agreement under section 1395cc of this title.

A hospital with respect to which an agreement under this section has been terminated shall not be eligible to enter into a new agreement until a two-year period has elapsed from the termination date.

(d) Post-hospital extended care services

Any agreement with a hospital under this section shall provide that payment for services will be made only for services for which payment would be made as post-hospital extended care services if those services had been furnished by a skilled nursing facility under an agreement entered into under section 1395cc of this title; and any individual who is furnished services, for which payment may be made under an agreement under this section, shall, for purposes of this subchapter (other than this section), be deemed to have received post-hospital extended care services in like manner and to the same extent as if the services furnished to him had been post-hospital extended care services furnished by a skilled nursing facility under an agreement under section 1395cc of this title.

(e) Reimbursement for routine hospital services

During a period for which a hospital has in effect an agreement under this section, in order to allocate routine costs between hospital and long-term care services for purposes of determining payment for inpatient hospital services, the total reimbursement due for routine services from all classes of long-term care patients (including this subchapter, subchapter XIX of this chapter, and private pay patients) shall be subtracted from the hospital's total routine costs before calculations are made to determine this subchapter reimbursement for routine hospital services.

(f) Conditions applicable to skilled nursing facilities

A hospital which enters into an agreement with the Secretary under this section shall be required to meet those conditions applicable to skilled nursing facilities relating to discharge planning and the social services function (and staffing requirements to satisfy it) which are promulgated by the Secretary under section 1395i-3 of this title. Services furnished by such a hospital which would otherwise constitute post-hospital extended care services if furnished by a skilled nursing facility shall be subject to the same requirements applicable to such services when furnished by a skilled nursing facility except for those requirements the Secretary determines are inappropriate in the case of these services being furnished by a hospital under this section.

(g) Agreements on demonstration basis

The Secretary may enter into an agreement under this section on a demonstration basis with any hospital which does not meet the requirement of subsection (b)(1) of this section, if the hospital otherwise meets the requirements of this section.

(Aug. 14, 1935, ch. 531, title XVIII, Sec. 1883, as added Pub. L. 96-499, title IX, Sec. 904(a)(1), Dec. 5, 1980, 94 Stat. 2615; amended Pub. L. 100-203, title IV, Secs. 4005(b)(1), (2), 4201(d)(3), Dec. 22, 1987, 101 Stat. 1330-48, as amended Pub. L. 100-360, title IV, Sec. 411(l)(1)(C), July 1, 1988, as added Pub. L. 100-485, title VI, Sec. 608(d)(27)(B), Oct. 13, 1988, 102 Stat. 2422; Pub. L. 100-360, title I, Sec. 104(d)(6), title IV, Sec. 411(b)(4)(D), July 1, 1988, 102 Stat. 689, 770; Pub. L. 101-234, title I, Sec.

101(a), Dec. 13, 1989, 103 Stat. 1979; Pub. L. 101-508, title IV, Sec. 4008(j)(1), Nov. 5, 1990, 104 Stat. 1388-51; Pub. L. 105-33, title IV, Sec. 4432(b)(5)(G), Aug. 5, 1997, 111 Stat. 422; Pub. L. 106-113, div. B, Sec. 1000(a)(6) [title IV, Secs. 403(f), 408(a), (b)], Nov. 29, 1999, 113 Stat. 1536, 1501A-371, 1501A-375.)

PART 409--HOSPITAL INSURANCE BENEFITS

Subpart C—Posthospital SNF Care

§ 409.20 Coverage of services.

(a) *Included services.* Subject to the conditions and limitations set forth in this subpart and subpart D of this part, “posthospital SNF care” means the following services furnished to an inpatient of a participating SNF, or of a participating hospital or critical access hospital (CAH) that has a swing-bed approval:

(1) Nursing care provided by or under the supervision of a registered professional nurse.

(2) Bed and board in connection with the furnishing of that nursing care.

(3) Physical, occupational, or speech therapy.

(4) **Medical social services.**

(5) Drugs, biologicals, supplies, appliances, and equipment.

(6) Services furnished by a hospital with which the SNF has a transfer agreement in effect under § 483.75(n) of this chapter.

(7) Other services that are generally provided by (or under arrangements made by) SNFs.

(b) *Excluded services*—(1) *Services that are not considered inpatient hospital services.*

No service is included as posthospital SNF care if it would not be included as an inpatient hospital service under §§ 409.11 through 409.18.

(2) *Services not generally provided by (or under arrangements made by) SNFs.*

Except as specifically listed in §§ 409.21 through 409.27, only those services

generally provided by (or under arrangements made by) SNFs are considered as posthospital SNF care. For example, a type of medical or surgical procedure that is ordinarily performed only on an inpatient basis in a hospital is not included as “posthospital SNF care,” because such procedures are not generally provided by (or under arrangements made by) SNFs.

(c) *Services not generally provided by (or under arrangements made by) SNFs.*

In § 409.21 through § 409.36—

(1) The terms *SNF* and *swing-bed hospital* are used when the context applies to the particular facility.

(2) The term *facility* is used to mean both SNFs and swing-bed hospitals.

(3) The term *swing-bed hospital* includes a CAH with swing-bed approval under subpart F of part 485 of this chapter.

(4) The term *post-hospital SNF care* includes SNF care that does not follow a hospital stay when the beneficiary is enrolled in a plan, as defined in § 422.4 of this chapter, offered by a Medicare+Choice (M+C) organization, that includes the benefits described in § 422.101(c) of this chapter.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985; 58 FR 30667, May 26, 1993; 63 FR 26306, May 12, 1998; 64 FR 3648, Jan. 25, 1999; 64 FR 41681, July 30, 1999; 68 FR 46070, Aug. 4, 2003; 68 FR 50854, Aug. 22, 2003]

PART 411--EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

§ 411.15 Particular services excluded from coverage.

The following services are excluded from coverage:

....

(p) *Services furnished to SNF residents*

—(1) *Basic rule.* Except as provided in paragraph (p)(2) of this section, any service furnished to a resident of an SNF during a covered Part A stay by an entity other than the SNF, unless the SNF has an arrangement (as defined in § 409.3 of this chapter) with that entity to furnish that particular service to the SNF's residents. Services subject to exclusion under this paragraph include, but are not limited to—

(i) Any physical, occupational, or speech-language therapy services, regardless of whether the services are furnished by (or under the supervision of) a physician or other health care professional, and regardless of whether the resident who receives the services is in a covered Part A stay; and

(ii) Services furnished as an incident to the professional services of a physician or other health care professional specified in paragraph (p)(2) of this section.

(2) *Exceptions.* The following services are not excluded from coverage, provided that the claim for payment includes the SNF's Medicare provider number in accordance with § 424.32(a)(5) of this chapter:

(i) Physicians' services that meet the criteria of § 415.102(a) of this chapter for payment on a fee schedule basis.

(ii) Services performed under a physician's supervision by a physician assistant who meets the applicable definition in section 1861(aa)(5) of the Act.

(iii) Services performed by a nurse practitioner or clinical nurse specialist who meets the applicable definition in section

1861(aa)(5) of the Act and is working in collaboration (as defined in section 1861(aa)(6) of the Act) with a physician.

(iv) Services performed by a certified nurse-midwife, as defined in section 1861(gg) of the Act.

(v) Services performed by a qualified psychologist, as defined in section 1861(ii) of the Act.

(vi) Services performed by a certified registered nurse anesthetist, as defined in section 1861(bb) of the Act.

(vii) Dialysis services and supplies, as defined in section 1861(s)(2)(F) of the Act, and those ambulance services that are furnished in conjunction with them.

(viii) Erythropoietin (EPO) for dialysis patients, as defined in section 1861(s)(2)(O) of the Act.

(ix) Hospice care, as defined in section 1861(dd) of the Act.

(x) An ambulance trip that initially conveys an individual to the SNF to be admitted as a resident, or that conveys an individual from the SNF in connection with one of the circumstances specified in paragraphs (p)(3)(i) through (p)(3)(iv) of this section as ending the individual's status as an SNF resident.

(xi) The transportation costs of electrocardiogram equipment (HCPCS code R0076), but only with respect to those electrocardiogram test services furnished during 1998.

(xii) Those chemotherapy items identified, as of July 1, 1999, by HCPCS codes J9000–J9020; J9040–J9151; J9170–J9185; J9200–J9201; J9206–J9208; J9211; J9230–J9245; and J9265–J9600; and, as of January 1, 2004, by HCPCS codes A9522 and A9523.

(xiii) Those chemotherapy administration services identified, as of July 1, 1999, by HCPCS codes 36260–36262; 36489;

36530–36535; 36640; 36823; and 96405–96542.

(xiv) Those radioisotope services identified, as of July 1, 1999, by HCPCS codes 79030–79440.

(xv) Those customized prosthetic devices (including artificial limbs and their components) identified, as of July 1, 1999,

by HCPCS codes L5050–L5340; L5500–L5611; L5613–L5986; L5988; L6050–L6370; L6400–6880; L6920–L7274; and L7362–L7366, which are delivered for a resident’s use during a stay in the SNF and intended to be used by the resident after discharge from the SNF.

.....

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

Subpart B—Requirements for Long Term Care Facilities

SOURCE: 54 FR 5359, Feb. 2, 1989, unless otherwise noted.

§ 483.15 Quality of life.

A facility must care for its residents in a manner and in an environment that promotes maintenance or enhancement of each resident's quality of life.

(a) *Dignity*. The facility must promote care for residents in a manner

and in an environment that maintains or enhances each resident's dignity and respect in full recognition of his or her individuality.

(b) *Self-determination and participation*. The resident has the right to—

(1) Choose activities, schedules, and health care consistent with his or her interests, assessments, and plans of care;

(2) Interact with members of the community both inside and outside the facility; and

(3) Make choices about aspects of his or her life in the facility that are significant to the resident.

(c) *Participation in resident and family groups*. (1) A resident has the right to organize and participate in resident groups in the facility;

(2) A resident's family has the right to meet in the facility with the families of other residents in the facility;

(3) The facility must provide a resident or family group, if one exists, with private space;

(4) Staff or visitors may attend meetings at the group's invitation;

(5) The facility must provide a designated staff person responsible for providing assistance and responding to written requests that result from group meetings;

(6) When a resident or family group exists, the facility must listen to the views and act

upon the grievances and recommendations of residents and families concerning proposed policy and operational decisions affecting resident care and life in the facility.

(d) *Participation in other activities*. A resident has the right to participate in social, religious, and community activities that do not interfere with the rights of other residents in the facility.

(e) *Accommodation of needs*. A resident has the right to—

(1) Reside and receive services in the facility with reasonable accommodation of individual needs and preferences, except when the health or safety of the individual or other residents would be endangered; and

(2) Receive notice before the resident's room or roommate in the facility is changed.

(f) *Activities*. (1) The facility must provide for an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interests and the physical, mental, and psychosocial well-being of each resident.

(2) The activities program must be directed by a qualified professional who—

(i) Is a qualified therapeutic recreation specialist or an activities professional who—

(A) Is licensed or registered, if applicable, by the State in which practicing; and

(B) Is eligible for certification as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body on or after October 1, 1990; or

(ii) Has 2 years of experience in a social or recreational program within the last 5 years, 1 of which was full-time in a patient activities program in a health care setting; or

(iii) Is a qualified occupational therapist or occupational therapy assistant; or

(iv) Has completed a training course approved by the State.

(g) **Social Services.** (1) The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

(2) A facility with more than 120 beds must employ a **qualified social worker** on a full-time basis.

(3) **Qualifications of social worker. A qualified social worker is an individual with—**

(i) A **bachelor's degree in social work or a bachelor's degree in a human services field including but not limited to sociology, special education, rehabilitation counseling, and psychology; and**

(ii) **One year of supervised social work experience in a health care setting** working directly with individuals.

(h) **Environment.** The facility must provide—

(1) A safe, clean, comfortable, and homelike environment, allowing the resident to use his or her personal belongings to the extent possible;

(2) Housekeeping and maintenance services necessary to maintain a sanitary, orderly, and comfortable interior;

(3) Clean bed and bath linens that are in good condition;

(4) Private closet space in each resident room, as specified in § 483.70(d)(2)(iv) of this part;

(5) Adequate and comfortable lighting levels in all areas;

(6) Comfortable and safe temperature levels. Facilities initially certified after October 1, 1990 must maintain a temperature range of 71–81°F; and

(7) For the maintenance of comfortable sound levels.

[56 FR 48871, Sept. 26, 1991, as amended at 57 FR 43924, Sept. 23, 1992]

§ 483.20 Resident assessment.

The facility must conduct initially and periodically a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity.

(a) **Admission orders.** At the time each resident is admitted, the facility must have physician orders for the resident's immediate care.

(b) **Comprehensive assessments.**

(1) **Resident assessment instrument.** A facility must make a comprehensive assessment of a resident's needs, using the resident assessment instrument (RAI) specified by the State. The assessment must include at least the following:

(i) Identification and demographic information.

(ii) Customary routine.

(iii) Cognitive patterns.

(iv) Communication.

(v) Vision.

(vi) Mood and behavior patterns.

(vii) Psychosocial well-being.

(viii) Physical functioning and structural problems.

(ix) Continence.

(x) Disease diagnoses and health conditions.

(xi) Dental and nutritional status.

(xii) Skin condition.

(xiii) Activity pursuit.

(xiv) Medications.

(xv) Special treatments and procedures.

(xvi) Discharge potential.

(xvii) Documentation of summary information regarding the additional assessment performed through the resident assessment protocols.

(xviii) Documentation of participation in assessment. The assessment process must include direct observation and communication with the resident, as well as communication with licensed and nonlicensed direct care staff members on all shifts.

(2) **When required.** Subject to the timeframes prescribed in § 413.343(b) of

this chapter, a facility must conduct a comprehensive assessment of a resident in accordance with the timeframes specified in paragraphs (b)(2) (i) through (iii) of this section. The timeframes prescribed in § 413.343(b) of this chapter do not apply to CAHs.

(i) Within 14 calendar days after admission, excluding readmissions in which there is no significant change in the resident's physical or mental condition. (For purposes of this section, "readmission" means a return to the facility following a temporary absence for hospitalization or for therapeutic leave.)

(ii) Within 14 calendar days after the facility determines, or should have determined, that there has been a significant change in the resident's physical or mental condition. (For purposes of this section, a "significant change" means a major decline or improvement in the resident's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the resident's health status, and requires interdisciplinary review or revision of the care plan, or both.)

(iii) Not less often than once every 12 months.

(c) *Quarterly review assessment.* A facility must assess a resident using the quarterly review instrument specified by the State and approved by CMS not less frequently than once every 3 months.

(d) *Use.* A facility must maintain all resident assessments completed within the previous 15 months in the resident's active record and use the results of the assessments to develop, review, and revise the resident's comprehensive plan of care.

(e) *Coordination.* A facility must coordinate assessments with the preadmission screening and resident review program under Medicaid in part 483, subpart C to the

maximum extent practicable to avoid duplicative testing and effort.

(f) *Automated data processing requirement.*

(1) *Encoding data.* Within 7 days after a facility completes a resident's assessment, a facility must encode the following information for each resident in the facility:

(i) Admission assessment.

(ii) Annual assessment updates.

(iii) Significant change in status assessments.

(iv) Quarterly review assessments.

(v) A subset of items upon a resident's transfer, reentry, discharge, and death.

(vi) Background (face-sheet) information, if there is no admission assessment.

(2) *Transmitting data.* Within 7 days after a facility completes a resident's assessment, a facility must be capable of transmitting to the State information for each resident contained in the

MDS in a format that conforms to standard record layouts and data dictionaries, and that passes standardized edits defined by CMS and the State.

(3) *Monthly transmittal requirements.* A facility must electronically transmit, at least monthly, encoded, accurate, complete MDS data to the State for all assessments conducted during the previous month, including the following:

(i) Admission assessment.

(ii) Annual assessment.

(iii) Significant change in status assessment.

(iv) Significant correction of prior full assessment.

(v) Significant correction of prior quarterly assessment.

(vi) Quarterly review.

(vii) A subset of items upon a resident's transfer, reentry, discharge, and death.

(viii) Background (face-sheet) information, for an initial transmission of MDS data on a resident that does not have an admission assessment.

(4) *Data format.* The facility must transmit data in the format specified by CMS or, for a State which has an alternate RAI approved by CMS, in the format specified by the State and approved by CMS.

(5) *Resident-identifiable information.* (i) A facility may not release information that is resident-identifiable to the public.

(ii) The facility may release information that is resident-identifiable to an agent only in accordance with a contract under which the agent agrees not to use or disclose the information except to the extent the facility itself is permitted to do so.

(g) *Accuracy of assessments.* The assessment must accurately reflect the resident's status.

(h) *Coordination.* A registered nurse must conduct or coordinate each assessment with the appropriate participation of health professionals.

(i) *Certification.* (1) A registered nurse must sign and certify that the assessment is completed.

(2) Each individual who completes a portion of the assessment must sign and certify the accuracy of that portion of the assessment.

(j) *Penalty for falsification.* (1) Under Medicare and Medicaid, an individual who willfully and knowingly—

(i) Certifies a material and false statement in a resident assessment is subject to a civil money penalty of not more than \$1,000 for each assessment; or

(ii) Causes another individual to certify a material and false statement in a resident assessment is subject to a civil money penalty of not more than \$5,000 for each assessment.

(2) Clinical disagreement does not constitute a material and false statement.

(k) *Comprehensive care plans.* (1) The facility must develop a comprehensive care plan for each resident that includes measurable objectives and timetables to meet a resident's medical, nursing, and

mental and psychosocial needs that are identified in the comprehensive assessment. The care plan must describe the following—

(i) The services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being as required under § 483.25; and

(ii) Any services that would otherwise be required under § 483.25 but are not provided due to the resident's exercise of rights under § 483.10, including the right to refuse treatment under § 483.10(b)(4).

(2) A comprehensive care plan must be—

(i) Developed within 7 days after completion of the comprehensive assessment;

(ii) Prepared by an interdisciplinary team, that includes the attending physician, a registered nurse with responsibility for the resident, and other appropriate staff in disciplines as determined by the resident's needs, and, to the extent practicable, the participation of the resident, the resident's family or the resident's legal representative; and

(iii) Periodically reviewed and revised by a team of qualified persons after each assessment.

(3) The services provided or arranged by the facility must—

(i) Meet professional standards of quality; and

(ii) Be provided by qualified persons in accordance with each resident's written plan of care.

(l) *Discharge summary.* When the facility anticipates discharge a resident must have a discharge summary that includes—

(1) A recapitulation of the resident's stay;

(2) A final summary of the resident's status to include items in paragraph

(b)(2) of this section, at the time of the discharge that is available for release to authorized persons and agencies, with the consent of the resident or legal representative; and

(3) A post-discharge plan of care that is developed with the participation of the resident and his or her family, which will assist the resident to adjust to his or her new living environment.

(m) *Preadmission screening for mentally ill individuals and individuals with mental retardation.*

(1) A nursing facility must not admit, on or after January 1, 1989, any new resident with—

(i) Mental illness as defined in paragraph (f)(2)(i) of this section, unless the State mental health authority has determined, based on an independent physical and mental evaluation performed by a person or entity other than the State mental health authority, prior to admission, (A) That, because of the physical and mental condition of the individual, the individual requires the level of services provided by a nursing facility; and

(B) If the individual requires such level of services, whether the individual requires specialized services; or

(ii) Mental retardation, as defined in paragraph (f)(2)(ii) of this section, unless the State mental retardation or developmental disability authority has determined prior to admission—

(A) That, because of the physical and mental condition of the individual, the individual requires the level of services provided by a nursing facility; and

(B) If the individual requires such level of services, whether the individual requires specialized services for mental retardation.

(2) *Definition.* For purposes of this section—

(i) An individual is considered to have *mental illness* if the individual has a serious mental illness as defined in § 483.102(b)(1).

(ii) An individual is considered to be *mentally retarded* if the individual is mentally retarded as defined in § 483.102(b)(3) or is a person with a related condition as described in 42 CFR

435.1009.

[56 FR 48871, Sept. 26, 1991, as amended at 57 FR 43924, Sept. 23, 1992; 62 FR 67211, Dec. 23, 1997; 63 FR 53307, Oct. 5, 1998; 64 FR 41543, July 30, 1999; 68 FR 46072, Aug. 4, 2003]

§ 483.25 Quality of care.

Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

(a) *Activities of daily living.* Based on the comprehensive assessment of a resident, the facility must ensure that—

(1) A resident's abilities in activities of daily living do not diminish unless circumstances of the individual's clinical condition demonstrate that diminution was unavoidable. This includes the resident's ability to—

(i) Bathe, dress, and groom;

(ii) Transfer and ambulate;

(iii) Toilet;

(iv) Eat; and

(v) Use speech, language, or other functional communication systems.

(2) A resident is given the appropriate treatment and services to maintain or improve his or her abilities specified in paragraph (a)(1) of this section; and

(3) A resident who is unable to carry out activities of daily living receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene.

(b) *Vision and hearing.* To ensure that residents receive proper treatment and assistive devices to maintain vision and hearing abilities, the facility must, if necessary, assist the resident—

(1) In making appointments, and

(2) By arranging for transportation to and from the office of a practitioner specializing in the treatment of vision or hearing

impairment or the office of a professional specializing in the provision of vision or hearing assistive devices.

(c) *Pressure sores*. Based on the comprehensive assessment of a resident, the facility must ensure that—

(1) A resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable; and

(2) A resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.

(d) *Urinary Incontinence*. Based on the resident's comprehensive assessment, the facility must ensure that—

(1) A resident who enters the facility without an indwelling catheter is not catheterized unless the resident's clinical condition demonstrates that catheterization was necessary; and

(2) A resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible.

(e) *Range of motion*. Based on the comprehensive assessment of a resident, the facility must ensure that—

(1) A resident who enters the facility without a limited range of motion does not experience reduction in range of motion unless the resident's clinical condition demonstrates that a reduction in range of motion is unavoidable; and

(2) A resident with a limited range of motion receives appropriate treatment and services to increase range of motion and/or to prevent further decrease in range of motion.

(f) ***Mental and Psychosocial functioning***. Based on the comprehensive assessment of a resident, the facility must ensure that—

(1) A resident who displays mental or psychosocial adjustment difficulty, receives

appropriate treatment and services to correct the assessed problem, and

(2) A resident whose assessment did not reveal a mental or psychosocial adjustment difficulty does not display a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors, unless the resident's clinical condition demonstrates that such a pattern was unavoidable.

.....
(2) *Antipsychotic Drugs*. Based on a comprehensive assessment of a resident, the facility must ensure that—

(i) Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and

(ii) Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.

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[56 FR 48873, Sept. 26, 1991, as amended at 57 FR 43925, Sept. 23, 1992]

Medicare Benefit Policy Manual
CHAPTER 8 - COVERAGE OF EXTENDED CARE (SNF) SERVICES UNDER HOSPITAL
INSURANCE

50.4 - Medical Social Services to Meet the Patient's Medically Related Social Needs

(Rev. 1, 10-01-03)

A3-3133.4, SNF-230.4

Medical social services are those social services, which contribute meaningfully to the treatment of a patient's condition. Such services include, but are not limited to:

- a. Assessment of the social and emotional factors related to the patient's illness, his or her need for care, response to treatment, and adjustment to care in the facility;
- b. Appropriate action to obtain case work services to assist in resolving problems in these areas; and
- c. Assessment of the relationship of the patient's medical and nursing requirements to his or her home situation, financial resources, and the community resources available to him or her in making the decision regarding their discharge.

Medicare Catastrophic Coverage Act of 1988

CONFERENCE REPORT 100-661

35. Protection of Income and Resources of Couple for Maintenance of Community Spouse (Section 302 of House bill; Section 14C of Senate amendment)

.....

The conferees wish to clarify the requirements in sections 4201 and 4211 of P.L. 100-203 that nursing facilities with more than 120 beds must have at least one **social worker** (with at least a **bachelor's degree in social work or similar professional qualification**) employed full-time to provide or assure the provision of social services. Facilities could meet this requirement by employing either a person with a degree in social work or with similar professional qualifications, such as a degree in a related field and previous supervised experience in meeting individual psycho-social needs. It is the intent of the conferees that the Secretary ensure that requirements regarding consultation and supervision of social work services be at least as stringent as those in effect prior to enactment of these changes.

LETTER TO HCFA FROM NASW ON PROPOSED RULE

Original Printed on Board Letterhead

February 28, 1994

Health Care Financing Administration
US Department of Health and Human Services
Attention: BPD—706—P
P.O. Box 26688
Baltimore, Maryland 21207

RE: Proposed Rule: Medicare Coverage and Payment for Clinical Social Worker Services/ File Code BPD—706—P

The following comments on the proposed rule to provide Medicare coverage and payment for clinical social worker services are submitted on behalf of the National Association of Social Workers (NASW). NASW represents 147,000 professional social workers, two—thirds of whom practice in health and mental health care settings.

Professional social workers provide a variety of services in health care settings, such as case management, discharge planning, health education and promotion, and assisting patients and their families to follow the treatment plan. The Medicare statute reflects this diversity, and a variety of social work services in health care settings are authorized through assorted sections of the statute, citing differing educational requirements for the social worker provider.

In general, NASW is concerned that the proposed rule to implement coverage and payment for clinical social worker services under the Part B outpatient mental health benefit appears to confuse clinical social worker services with other authorized social work services in health care settings. Consequently, the proposed rule places an unnecessary emphasis on the site of service, rather than the availability of clinical social worker services to Medicare beneficiaries. NASW contends that section 1861 (hh)(2) of the Act provides the specificity to avoid the confusion by limiting direct reimbursement under the Part B outpatient mental health benefit to the diagnosis and treatment of mental illnesses as performed by clinical social workers who meet the qualifications of section 1861(hh)(1). The proposed rule's over—emphasis on possible site of service coverage exclusions unnecessarily complicates the provision of clinical social worker services and may inappropriately deny beneficiaries access to the covered Medicare service.

Inpatient/Outpatient Hospital Services

NASW is aware that medical social services are a required service in hospitals

and that medical social services are "bundled" into the hospital's reimbursement rate. However, neither the Medicare statute nor regulations define the medical social services requirement nor the qualifications of professionals who may provide these services in the hospital. Accordingly, NASW has several concerns regarding the "bundling" issue as it relates to the Medicare, Part B, outpatient benefit for clinical social worker services, particularly in outpatient hospital psychiatric departments. If the diagnosis and treatment of mental illnesses and mental disorders provided by clinical social workers are indeed factored into the hospital's overall reimbursement rate, we would ask the following questions --

1. In what way are clinical social worker services currently mandated in outpatient hospital settings?
2. What are the quality assurance mechanisms that ensure clinical social worker services are made available to Medicare beneficiaries in outpatient hospital departments?

Reimbursement of Clinical Social Worker Services in Skilled Nursing Facilities

The Federal Register announcement invites comments regarding how to differentiate the level of services that would qualify under the statute as clinical social worker services performed in skilled nursing facilities (SNFs) from those services that are required by the SNF as a condition for participation. In considering this issue NASW believes it is very important to review the SNF requirements that were mandated through the Omnibus Budget Reconciliation Act of 1987.

SNF Requirements

1. The facility must provide medically related social services to attain the highest practical physical, mental, and psychosocial well-being of each resident.
2. A facility with more than 120 beds must employ a qualified social worker on a full-time basis. HCFA regulations define a "qualified social worker" for facilities over 120 beds as an individual with a bachelor's degree in social work or a related field and one year of supervised social work experience in a health care setting.

Issues

1. Clinical social worker services are defined by section 1861 (hh)(2) of the Social Security Act as the diagnosis and treatment of mental illnesses performed by a clinical social worker.

The diagnosis and treatment of mental illnesses is not analogous to the broad range of tasks expected of a SNF's social services provider. Nor, is the diagnosis and treatment of mental illnesses analogous to the SNF requirement to provide medically related social services "to attain or maintain the highest practical physical, mental, and psychosocial well-being of each resident." If HCFA believed that the latter were the case, then the need for clarification would extend far beyond the issue of reimbursement for clinical social worker services in SNFs. The issue would become whether reimbursement, under Part B, would be allowed for the diagnosis and treatment of mental illnesses of SNF residents by any mental health professional recognized by the statute, including clinical psychologists and psychiatrists.

2. "Clinical social worker" is defined in section 1861 (hh)(1) of the Social Security Act as an individual with a master's or doctoral degree in social work, 2 years post graduate, supervised clinical social work experience, and licensure or certification in the state where the services are performed.

Only in SNFs with over 120 beds is there any requirement that the facility employ a qualified social worker on a full—time basis. Most nursing homes have less than 120 beds and, consequently, have no requirement regarding the qualifications of their staff who provide social services. According to the most recent National Nursing Home Survey, approximately one—third of all facilities in the United States, at most, are required to hire an individual with a bachelor's degree in social work or another field with one year of experience. For those SNFs that are required to hire a "qualified social worker", by virtue of their size, the qualifications for the social services provider are far less than the qualifications of a clinical social worker.

NASW Recommendation

NASW recommends that clinical social worker services be reimbursed separate and apart from the reimbursement of a SNF, just as the mental health services provided by clinical psychologists and psychiatrists are independently reimbursed. Clinical social worker services may be easily distinguished from the social services requirement of SNFs by use of the International Classification of Diseases, 9th Revision, Clinical Modification (ICD—9—CM) coding system to describe the diagnosed mental illnesses and mental disorders when submitting Medicare, Part B, claims. The therapeutic services rendered would be reported using the appropriate psychiatry codes in the Physicians' Current Procedural Terminology (CPT) codes. Some of functions of the social services providers in SNFs are captured by the Evaluation and Management (E/M) CPT codes, rather than the reimbursable psychiatry codes.

Medicare Fee Schedule

In NASWs view, a serious statutory problem exists in the Medicare payment methodology for clinical social worker services. Section 1833(a)(1)(F) of the Act establishes payment for clinical social worker services at the lesser of the actual charge or 75 percent of the amount determined for payment for clinical psychologists' services. Payment for therapeutic services provided by a psychologist, in turn, may not exceed 80 percent of a psychiatrist's charge. We believe that this methodology does little more than establish a pecking order in the valuation of services provided by the three categories of mental health providers that are currently recognized by the Medicare Program. The current methodology does not bear any direct relationship to the average charges of the three categories of providers outside of the Medicare Program, not does the methodology correspond with those established for other non—physician practitioners in Medicare. At no other point in the statute is the fee schedule for one non—physician provider tied to the fee of another non—physician provider.

The statutory methodology for establishing clinical social workers' fees places the clinical social worker in the unenviable position of being the lowest paid non—physician practitioner under Medicare, with reimbursement set at 60% of a physician's fee. It is NASWs position that the statute must be amended in order to develop an equitable reimbursement methodology for clinical social worker services, similar to that proposed by the Physician Payment Review Commission in 1991, that takes into account the practitioner's investment in education and training, office expenses, and malpractice costs. In the meantime, however, NASW encourages HCFA to reevaluate the current application of the Resource—Based Relative Value Scale for outpatient mental health services provided by psychiatrists to ensure that the RVU payment system adequately reflects cognitive services such as psychotherapy.

Consultation with the Patient's Primary Care Physician

Good clinical practice for any mental health professional will include appropriate consultation with the client's primary care physician to determine whether medical conditions or medication may be contributing to the individual's mental health problem. For Medicare beneficiaries, who are eligible for the program benefits by virtue of their age or disability, a consultation requirement is most certainly appropriate.

While the consultation requirement is appropriate, two suggested procedures to implement the requirement that are contained in the proposed rule appear excessive --the required yearly attestation for consultation and the requirement that a clinical social worker submit a written request for consultation after four unsuccessful attempts have been made to contact the primary care physician by telephone.

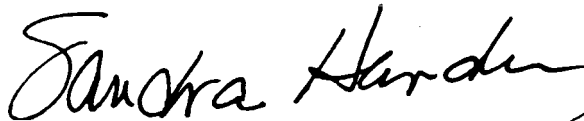
In the first example, yearly attestations for physician consultation are unnecessary if the mental health professional has already signed such an attestation when applying for a Medicare provider identification number. Yearly attestations simply add administrative costs and burdens to the Medicare Program. With respect to the proposed requirement that clinical social workers contact the primary care physician in writing after four unsuccessful attempts have been made to reach the physician by telephone, NASW suggests that the rule simply state that the patient's records reflect a good faith attempt to consult with the primary care physician.

Psychological Testing

NASW believes that HCFA must revise the proposed rule to accommodate psychological testing that is provided by clinical social workers and other non—psychologists. Psychological tests are appropriately administered by clinical social workers and other trained mental health professionals and provide useful, objective assessment tools.

I hope you will find our comments helpful as you finalize the rule to implement Medicare coverage and reimbursement for clinical social worker services. Should you have any questions or require additional information, please do not hesitate to contact me at (202) 336—8261.

Sincerely,

A handwritten signature in black ink that reads "Sandra Harding". The signature is fluid and cursive, with a small horizontal line at the end.

Sandra Harding, ACSW Government Relations Associate

HOSPICE CARE – MEDICAL SOCIAL SERVICES/SOCIAL WORKER

Medicare coverage was extended to hospice care services beginning in November 1983 because of the Tax Equity and Fiscal Responsibility Act of 1982. "Hospice care is a method for caring for the terminally ill that helps those individuals continue their lives with as little disruption as possible. This type of care emphasizes supportive services, such as home care and pain control, rather than the cure-oriented services provided in institutions that are otherwise the primary focus of the Medicare program."⁸ Medicare defines "terminally ill" as an individual who has a medical prognosis of a six month or less life expectancy.

A terminally ill beneficiary may elect to receive hospice services for two 90-day periods and an unlimited number of subsequent 60-day periods each during the individual's lifetime, with each period needing to be requested and approved (Section 1812(a) and (d)).

A hospice program, as defined in Title XVIII of the Social Security Act, must be administered by a public agency or private organization (or a subdivision thereof) that provides care and services on a 24-hour basis in a patient's home, on an outpatient basis, and on a short-term inpatient basis. Physicians' services, nursing services, medical social services under the direction of a physician, and counseling services are defined in the law as core services and must be provided directly by hospice staff.

Although the regulations provide no guidance in terms of what is meant by medical social services, the regulations define "counseling" as helping both the terminally ill patient and the family member or other caregiver to deal with the patient's impending death. According to the regulations, counseling can be in the form of bereavement, spiritual, or additional counseling. Bereavement counseling, under the supervision of a qualified professional, is required following the patient's death, although Medicare does not provide any reimbursement for this service. The regulation requires the social worker to have at least a bachelor's degree in social work from a school accredited or approved by the Council on Social Work Education and identifies the counselor only as a "qualified individual or professional."

One social worker is included in the mandatory professionals that must serve on a hospice interdisciplinary group. The other required professionals are a physician, a nurse, and at least one pastoral or other counselor. This group is responsible for establishing a written plan of care for each patient (including review and update of such plans), defining hospice policies related to the day-by-day operations, and overseeing the delivery and management of hospice care and services.

⁸ 1990 Medicare Explained. (1990). Chicago: Commerce Clearing House, Inc.

SOCIAL SECURITY ACT § 1812

42USC1395d

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part A--Hospital Insurance Benefits for Aged and Disabled

Sec. 1395d. Scope of benefits

(a) Entitlement to payment for inpatient hospital services, post-hospital extended care services, home health services, and hospice care

The benefits provided to an individual by the insurance program under this part shall consist of entitlement to have payment made on his behalf or, in the case of payments referred to in section 1395f(d)(2) of this title to him (subject to the provisions of this part) for--

(1) inpatient hospital services or inpatient critical access hospital services for up to 150 days during any spell of illness minus 1 day for each day of such services in excess of 90 received during any preceding spell of illness (if such individual was entitled to have payment for such services made under this part unless he specifies in accordance with regulations of the Secretary that he does not desire to have such payment made);

(2)(A) post-hospital extended care services for up to 100 days during any spell of illness, and (B) to the extent provided in subsection (f) of this section, extended care services that are not post-hospital extended care services;

(3) for individuals not enrolled in part B of this subchapter, home health services, and for individuals so enrolled, post-institutional home health services furnished during a home health spell of illness for up to 100 visits during such spell of illness; and

(4) in lieu of certain other benefits, hospice care with respect to the individual during up to two periods of 90 days each and an unlimited number of subsequent periods of 60 days each with respect to which the individual makes an election under subsection (d)(1) of this section.

(b) Services not covered

Payment under this part for services furnished an individual during a spell of illness may not (subject to subsection (c) of this section) be made for--

(1) inpatient hospital services furnished to him during such spell after such services have been furnished to him for 150 days during such spell minus 1 day for each day of inpatient hospital services in excess of 90 received during any preceding spell of illness (if such individual was entitled to have payment for such

services made under this part unless he specifies in accordance with regulations of the Secretary that he does not desire to have such payment made);

(2) post-hospital extended care services furnished to him during such spell after such services have been furnished to him for 100 days during such spell; or

(3) inpatient psychiatric hospital services furnished to him after such services have been furnished to him for a total of 190 days during his lifetime.

Payment under this part for post-institutional home health services furnished an individual during a home health spell of illness may not be made for such services beginning after such services have been furnished for a total of 100 visits during such spell.

(c) Inpatients of psychiatric hospitals

If an individual is an inpatient of a psychiatric hospital on the first day of the first month for which he is entitled to benefits under this part, the days on which he was an inpatient of such a hospital in the 150-day period immediately before such first day shall be included in determining the number of days limit under subsection (b)(1) of this section insofar as such limit applies to (1) inpatient psychiatric hospital services, or (2) inpatient hospital services for an individual who is an inpatient primarily for the diagnosis or treatment of mental illness (but shall not be included in determining such number of days limit insofar as it applies to other inpatient hospital services or in determining the 190-day limit under subsection (b)(3) of this section).

(d) Hospice care; election; waiver of rights; revocation; change of election

(1) Payment under this part may be made for hospice care provided with respect to an individual only during two periods of 90 days each and an unlimited number of subsequent periods of 60 days each during the individual's lifetime and only, with respect to each such period, if the individual makes an election under this paragraph to receive hospice care under this part provided by, or under arrangements made by, a particular hospice program instead of certain other benefits under this subchapter.

(2)(A) Except as provided in subparagraphs (B) and (C) and except in such exceptional and unusual circumstances as the Secretary may provide, if an individual makes such an election for a period with respect to a particular hospice program, the individual shall be deemed to have waived all rights to have payment made under this subchapter with respect to--

(i) hospice care provided by another hospice program (other than under arrangements made by the particular hospice program) during the period, and

(ii) services furnished during the period that are determined (in accordance with guidelines of the Secretary) to be--

(I) related to the treatment of the individual's condition with respect to which a diagnosis of terminal illness has been made or

(II) equivalent to (or duplicative of) hospice care; except that clause (ii) shall not apply to physicians' services furnished by the individual's attending physician (if not an employee of the hospice program) or to services provided by (or under arrangements made by) the hospice program.

(B) After an individual makes such an election with respect to a 90-day period or a subsequent 60-day period, the individual may revoke the election during the period, in which case--

(i) the revocation shall act as a waiver of the right to have payment made under this part for any hospice care benefits for the remaining time in such period and (for purposes of subsection (a)(4) of this section and subparagraph (A)) the individual shall be deemed to have been provided such benefits during such entire period, and

(ii) the individual may at any time after the revocation execute a new election for a subsequent period, if the individual otherwise is entitled to hospice care benefits with respect to such a period.

(C) An individual may, once in each such period, change the hospice program with respect to which the election is made and such change shall not be considered a revocation of an election under subparagraph (B).

(D) For purposes of this subchapter, an individual's election with respect to a hospice program shall no longer be considered to be in effect with respect to that hospice program after the date the individual's revocation or change of election with respect to that election takes effect.

(e) Services taken into account

For purposes of subsections (b) and (c) of this section, inpatient hospital services, inpatient psychiatric hospital services, and post-hospital extended care services shall be taken into account only if payment is or would be, except for this section or the failure to comply with the request and certification requirements of or under section 1395f(a) of this title, made with respect to such services under this part.

.....

(Aug. 14, 1935, ch. 531, title XVIII, Sec. 1812, as added Pub. L. 89-97, title I, Sec. 102(a), July 30, 1965, 79 Stat. 291; amended Pub. L. 90-248, title I, Secs. 129(c)(2), 137(a), 138(a), 143(b), 146(a), Jan. 2, 1968, 81 Stat. 847, 853, 854, 857, 859; Pub. L. 96-499, title IX, Secs. 930(b)-(d), 931(a), Dec. 5, 1980, 94 Stat. 2631, 2633; Pub. L. 97-35, title XXI, Sec. 2121(a), Aug. 13, 1981, 95 Stat. 796; Pub. L. 97-248, title I, Secs. 122(b), 123, Sept. 3, 1982, 96 Stat. 356, 364; Pub. L. 97-448, title III, Sec. 309(b)(5), Jan. 12, 1983, 96 Stat. 2409; Pub. L. 100-360, title I, Sec. 101, July 1, 1988, 102 Stat. 684; Pub. L. 101-234, title I, Sec. 101(a), Dec. 13, 1989, 103 Stat. 1979; Pub. L. 101-239, title VI, Sec. 6003(g)(3)(B)(i), Dec. 19, 1989, 103 Stat. 2152; Pub. L. 101-508, title IV, Sec. 4006(a), Nov. 5, 1990, 104 Stat. 1388-43; Pub. L. 103-432, title I, Sec. 102(g)(1), Oct. 31, 1994, 108 Stat. 4404; Pub. L. 105-33, title IV, Secs. 4201(c)(1), 4443(a), (b)(1), 4611(a), Aug. 5, 1997, 111 Stat. 373, 423, 472; Pub. L. 106-113, div. B, Sec. 1000(a)(6) [title III, Sec. 321(k)(1)], Nov. 29, 1999, 113 Stat. 1536, 1501A-366.)

SOCIAL SECURITY ACT § 1814

42USC1395f

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part A--Hospital Insurance Benefits for Aged and Disabled

Sec. 1395f. Conditions of and limitations on payment for services

(a) Requirement of requests and certifications

Except as provided in subsections (d) and (g) of this section and in section 1395mm of this title, payment for services furnished an individual may be made only to providers of services which are eligible therefor under section 1395cc of this title and only if--

(1) written request, signed by such individual, except in cases in which the Secretary finds it impracticable for the individual to do so, is filed for such payment in such form, in such manner, and by such person or persons as the Secretary may by regulation prescribe, no later than the close of the period of 3 calendar years following the year in which such services are furnished (deeming any services furnished in the last 3 calendar months of any calendar year to have been furnished in the succeeding calendar year) except that where the Secretary deems that efficient administration so requires, such period may be reduced to not less than 1 calendar year;

(2) a physician, or, in the case of services described in subparagraph (B), a physician, or a nurse practitioner or clinical nurse specialist who does not have a direct or indirect employment relationship with the facility but is working in collaboration with a physician, certifies (and recertifies, where such services are furnished over a period of time, in such cases, with such frequency, and accompanied by such supporting material, appropriate to the case involved, as may be provided by regulations, except that the first of such recertifications shall be required in each case of inpatient hospital services not later than the 20th day of such period) that--

(A) in the case of inpatient psychiatric hospital services, such services are or were required to be given on an inpatient basis, by or under the supervision of a physician, for the psychiatric treatment of an individual; and (i) such treatment can or could reasonably be expected to improve the condition for which such treatment is or was necessary or (ii) inpatient diagnostic study is or was medically required and such services are or were necessary for such purposes;

(B) in the case of post-hospital extended care services, such services are or were required to be given because the individual needs or needed on a daily basis skilled nursing care (provided directly by or requiring the supervision of skilled nursing personnel) or other skilled rehabilitation services, which as a practical matter can only be provided in a skilled nursing facility on an inpatient basis, for any of the conditions with respect to which he was receiving inpatient hospital services (or services which would constitute inpatient hospital services if the institution met the requirements of paragraphs (6) and (9) of section 1395x(e) of this title) prior to transfer to the skilled nursing facility or for a condition requiring such extended care services which arose after such transfer and while he was still in the facility for treatment of the condition or conditions for which he was receiving such inpatient hospital services;

(C) in the case of home health services, such services are or were required because the individual is or was confined to his home (except when receiving items and services referred to in section 1395x(m)(7) of this title) and needs or needed skilled nursing care (other than solely venipuncture for the purpose of obtaining a blood sample) on an intermittent basis or physical or speech therapy or, in the case of an individual who has been furnished home health services based on such a need and who no longer has such a need for such care or therapy, continues or continued to need occupational therapy; a plan for furnishing such services to such individual has been established and is periodically reviewed by a physician; and such services are or were furnished while the individual was under the care of a physician; or

(D) in the case of inpatient hospital services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, the individual, because of his underlying medical condition and clinical status or because of the severity of

the dental procedure, requires hospitalization in connection with the provision of such services;

(3) with respect to inpatient hospital services (other than inpatient psychiatric hospital services) which are furnished over a period of time, a physician certifies that such services are required to be given on an inpatient basis for such individual's medical treatment, or that inpatient diagnostic study is medically required and such services are necessary for such purpose, except that (A) such certification shall be furnished only in such cases, with such frequency, and accompanied by such supporting material, appropriate to the cases involved, as may be provided by regulations, and (B) the first such certification required in accordance with clause (A) shall be furnished no later than the 20th day of such period;

(4) in the case of inpatient psychiatric hospital services, the services are those which the records of the hospital indicate were furnished to the individual during periods when he was receiving (A) intensive treatment services, (B) admission and related services necessary for a diagnostic study, or (C) equivalent services;

(5) with respect to inpatient hospital services furnished such individual after the 20th day of a continuous period of such services, there was not in effect, at the time of admission of such individual to the hospital, a decision under section 1395cc(d) of this title (based on a finding that utilization review of long-stay cases is not being made in such hospital);

(6) with respect to inpatient hospital services or post-hospital extended care services furnished such individual during a continuous period, a finding has not been made (by the physician members of the committee or group, as described in section 1395x(k)(4) of this title, including any finding made in the course of a sample or other review of admissions to the institution) pursuant to the system of utilization review that further inpatient hospital services or further post-hospital extended care services, as the case may be, are not medically necessary; except that, if such a finding has been made, payment may be made for such services furnished before the 4th day after the day on which the hospital or skilled nursing facility, as the case may be, received notice of such finding;

(7) in the case of hospice care provided an individual--

(A)(i) in the first 90-day period--

(I) the individual's attending physician (as defined in section 1395x(dd)(3)(B) of this title), and

(II) the medical director (or physician member of the interdisciplinary group described in section 1395x(dd)(2)(B) of this title) of the hospice program providing (or arranging for) the care, each certify in writing at the beginning of the period, that the individual is terminally ill (as defined in section 1395x(dd)(3)(A) of this title), and

(ii) in a subsequent 90- or 60-day period, the medical director or physician described in clause (i)(II) recertifies at the beginning of the period that the individual is terminally ill.

(B) a written plan for providing hospice care with respect to such individual has been established (before such care is provided by, or under arrangements made by, that hospice program) and is periodically reviewed by the individual's attending physician and by the medical director (and the interdisciplinary group described in section 1395x(dd)(2)(B) of this title) of the hospice program; and

(C) such care is being or was provided pursuant to such plan of care; and

(8) in the case of inpatient critical access hospital services, a physician certifies that the individual may reasonably be expected to be discharged or transferred to a hospital within 96 hours after admission to the critical access hospital.

SOCIAL SECURITY ACT § 1861

42USC1395x

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part D--Miscellaneous Provisions

Sec. 1395x. Definitions

dd) Hospice care; hospice program; definitions; certification; waiver by Secretary

(1) The term ``hospice care" means the following items and services provided to a terminally ill individual by, or by others under arrangements made by, a hospice program under a written plan (for providing such care to such individual) established and periodically reviewed by the individual's attending physician and by the medical director (and by the interdisciplinary group described in paragraph (2)(B)) of the program--

(A) nursing care provided by or under the supervision of a registered professional nurse,

(B) physical or occupational therapy, or speech-language pathology services,

(C) **medical social services** under the direction of a physician,

(D)(i) services of a home health aide who has successfully completed a training program approved by the Secretary and (ii) homemaker services,

(E) medical supplies (including drugs and biologicals) and the use of medical appliances, while under such a plan,

(F) physicians' services,

(G) short-term inpatient care (including both respite care and procedures necessary for pain control and acute and chronic symptom management) in an inpatient facility meeting such conditions as the Secretary determines to be appropriate to provide such care, but such respite care may be provided only on an intermittent, nonroutine, and occasional basis and may not be provided consecutively over longer than five days,

(H) **counseling** (including dietary counseling) with respect to care of the terminally ill individual and adjustment to his death, and

(I) any other item or service which is specified in the plan and for which payment may otherwise be made under this subchapter.

The care and services described in subparagraphs (A) and (D) may be provided on a 24-hour, continuous basis only during periods of crisis (meeting criteria established by the Secretary) and only as necessary to maintain the terminally ill individual at home.

(2) The term ``hospice program" means a public agency or private organization (or a subdivision thereof) which--

(A)(i) is primarily engaged in providing the care and services described in paragraph (1) and makes such services available (as needed) on a 24-hour basis and which also provides **bereavement counseling** for the immediate family of terminally ill individuals,

(ii) provides for such care and services in individuals' homes, on an outpatient basis, and on a short-term inpatient basis, directly or under arrangements made by the agency or organization, except that--

(I) the agency or organization must routinely provide directly substantially all of each of the services described in subparagraphs (A), (C), and (H) of paragraph (1), except as otherwise provided in paragraph (5), and

(II) in the case of other services described in paragraph (1) which are not provided directly by the agency or organization, the agency or organization must maintain professional management responsibility for all such services furnished to an individual, regardless of the location or facility in which such services are furnished; and

(iii) provides assurances satisfactory to the Secretary that the aggregate number of days of inpatient care described in paragraph (1)(G) provided in any 12-month period to individuals who have an election in effect under section 1395d(d) of this title with respect to that agency or organization does not exceed 20 percent of the aggregate number of days during that period on which such elections for such individuals are in effect;

(B) has an interdisciplinary group of personnel which--

(i) includes at least--

(I) one physician (as defined in subsection (r)(1) of this section),

(II) one registered professional nurse, and

(III) **one social worker**,

employed by or, in the case of a physician described in subclause (I), under contract with the agency or organization, and also includes at least one pastoral or other counselor,

(ii) provides (or supervises the provision of) the care and services described in paragraph (1), and

(iii) establishes the policies governing the provision of such care and services;

(C) maintains central clinical records on all patients;

(D) does not discontinue the hospice care it provides with respect to a patient because of the inability of the patient to pay for such care;

(E) (i) utilizes volunteers in its provision of care and services in accordance with standards set by the Secretary, which standards shall ensure a continuing level of effort to utilize such volunteers, and (ii) maintains records on the use of these volunteers and the cost savings and expansion of care and services achieved through the use of these volunteers;

(F) in the case of an agency or organization in any State in which State or applicable local law provides for the licensing of agencies or organizations of this nature, is licensed pursuant to such law; and

(G) meets such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are provided care and services by such agency or organization.

PART 418 – HOSPICE CARE

Subpart A – General Provision and Definitions

§ 418.3 Definitions.

...**Social worker** means a person who has at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education...

[48 FR 56026, Dec. 16, 1983, as amended at 52 FR 4499, Feb. 12, 1987; 50 FR 50834, Dec. 11, 1990]

.....

Subpart C – Conditions of Participation

§ 418.68 Condition of participation—**Interdisciplinary group.**

The hospice must designate an interdisciplinary group or groups composed of individuals who provide or supervise the care and services offered by the hospice.

(a) *Standard: Composition of group.*

The hospice must have an interdisciplinary group or groups that include at least the following individuals who are employees of the hospice:

- (1) A doctor of medicine or osteopathy.
- (2) A registered nurse.

(3) **A social worker.**

- (4) A pastoral or other counselor.

(b) *Standard: Role of group.* The

interdisciplinary group is responsible for—

- (1) Participation in the establishment of the plan of care;
- (2) Provision or supervision of hospice care and services;
- (3) Periodic review and updating of the plan of care for each individual receiving hospice care; and
- (4) Establishment of policies governing the day-to-day provision of hospice care and services.

(c) If a hospice has more than one interdisciplinary group, it must designate in advance the group it chooses to execute the functions described in paragraph (b)(4) of this section.

(d) *Standard: Coordinator.* The hospice must designate a registered nurse to coordinate the implementation of the plan of care for each patient.

.....

Subpart D—Conditions of Participation: Core Services

§ 418.80 Condition of participation—**Furnishing of core services.**

Except as permitted in § 418.83, a hospice must ensure that substantially all the core services described in this subpart are routinely provided directly by hospice employees. A hospice may use contracted staff if necessary to supplement hospice employees in order to meet the needs of patients during periods of peak patient loads or under extraordinary circumstances. If contracting is used, the hospice must maintain professional, financial, and administrative responsibility for the services and must assure that the qualifications of staff and services provided meet the requirements specified in this subpart.

[52 FR 7416, Mar. 11, 1987, as amended at 55 FR 50835, Dec. 11, 1990]

...

§ 418.84 Condition of participation—**Medical social services.**

Medical social services must be provided by a **qualified social worker**, under the direction of a physician.

...

§ 418.88 Condition of participation—**Counseling services.**

Counseling services must be available to both the individual and the family. Counseling includes bereavement

counseling, provided after the patient's death as well as dietary, spiritual and any other counseling services for the individual and family provided while the individual is enrolled in the hospice.

(a) *Standard: Bereavement counseling.*

There must be an organized program for the provision of bereavement services under the supervision of a qualified professional. The plan of care for these services should reflect family needs, as well as a clear delineation of services to be provided and the frequency of service delivery (up to one year following the death of the patient).

A special coverage provision for bereavement counseling is specified § 418.204(c).

...

(c) *Standard: Spiritual counseling.*

Spiritual counseling must include notice to patients as to the availability of clergy as provided in § 418.70(f).

(d) *Standard: Additional counseling.*

Counseling may be provided by other members of the interdisciplinary group as well as by other qualified professionals as determined by the hospice.

...

Subpart F—Covered Services

§ 418.200 Requirements for coverage.

To be covered, hospice services must meet the following requirements. They must be reasonable and necessary for the palliation or management of the terminal illness as well as related conditions.

The individual must elect hospice care in accordance with § 418.24 and a plan of care must be established as set forth in § 418.58 before services are provided. The services must be consistent with the plan of care. A certification that the individual is terminally ill must be completed as set forth in § 418.22.

§ 418.202 Covered services.

All services must be performed by appropriately qualified personnel, but it is the nature of the service, rather than the qualification of the person who provides it, that determines the coverage category of the service. The following services are covered hospice services:

(a) Nursing care provided by or under the supervision of a registered nurse.

(b) **Medical social services provided by a social worker** under the direction of a physician.

.....

(d) Counseling services provided to the terminally ill individual and the family members or other persons caring for the individual at home. Counseling, including dietary counseling, may be provided both for the purpose of training the individual's family or other caregiver to provide care, and for the purpose of helping the individual and those caring for him or her to adjust to the individual's approaching death.

(e) Short-term inpatient care provided in a participating hospice inpatient unit, or a participating hospital or SNF, that additionally meets the standards in § 418.202 (a) and (e) regarding staffing and patient areas. Services provided in an inpatient setting must conform to the written plan of care. Inpatient care may be required for procedures necessary for pain control or acute or chronic symptom management. Inpatient care may also be furnished as a means of providing respite for the individual's family or other persons caring for the individual at home. Respite care must be furnished as specified in § 418.98(b). Payment for inpatient care will be made at the rate appropriate to the level of care as specified in § 418.302.

(f) Medical appliances and supplies, including drugs and biologicals. Only drugs as defined in section 1861(t) of the Act and which are used primarily for the relief of pain and symptom control related to the

individual's terminal illness are covered. Appliances may include covered durable medical equipment as described in § 410.38 of this chapter as well as other self-help and personal comfort items related to the palliation or management of the patient's terminal illness. Equipment is provided by the hospice for use in the patient's home while he or she is under hospice care. Medical supplies include those that are part of the written plan of care.

(g) *Home health aide services furnished by qualified aides as designated in § 418.94 and homemaker services.* Home health aides may provide personal care services as defined in § 409.45(b) of this chapter. Aides may perform household services to maintain a safe and sanitary environment in areas of the home used by the patient, such as changing bed linens or light cleaning and laundering essential to the comfort and cleanliness of the patient. Aide services must be provided under the general supervision of a registered nurse.

Homemaker services may include assistance in maintenance of a safe and healthy environment and services to enable the individual to carry out the treatment plan.

(h) Physical therapy, occupational therapy and speech-language pathology services in addition to the services described in § 409.33 (b) and (c) of this chapter provided for purposes of symptom control or to

enable the patient to maintain activities of daily living and basic functional skills.

[48 FR 56026, Dec. 16, 1983, as amended at 51 FR 41351, Nov. 14, 1986; 55 FR 50835, Dec. 11, 1990; 59 FR 65498, Dec. 20, 1994]

§ 418.204 Special coverage requirements.

(a) *Periods of crisis.* Nursing care may be covered on a continuous basis for as much as 24 hours a day during periods of crisis as necessary to maintain an individual at home. Either homemaker or home health aide services or both may be covered on a 24-hour continuous basis during periods of crisis but care during these periods must be predominantly nursing care. A period of crisis is a period in which the individual requires continuous care to achieve palliation or management of acute medical symptoms.

(b) *Respite care.* (1) Respite care is short-term inpatient care provided to the individual only when necessary to relieve the family members or other persons caring for the individual.

(2) Respite care may be provided only on an occasional basis and may not be reimbursed for more than five consecutive days at a time.

(c) *Bereavement counseling.* Bereavement counseling is a required hospice service but it is not reimbursable.

[48 FR 56026, Dec. 16, 1983, as amended at 55 FR 50835, Dec. 11, 1990]

Medicare Benefit Policy Manual
CHAPTER 9 - COVERAGE OF HOSPICE SERVICES UNDER HOSPITAL
INSURANCE

40.1.2 - Medical Social Services

(Rev. 1, 10-01-03)

A3-3143.1.B, HO-230.1.B

Medical social services must be provided by a **social worker** who has at least a bachelor's degree from a **school accredited or approved by the Council on Social Work Education**, and who is working under the direction of a physician.

Services of these professionals which may be covered include, but are not limited to:

1. **Assessment** of the social and emotional factors related to the patient's illness, need for care, response to treatment and adjustment to care;
2. **Assessment** of the relationship of the patient's medical and nursing requirements to the patient's home situation, financial resources and availability of community resources;
3. **Appropriate action to obtain available community resources** to assist in resolving the patient's problem (**NOTE:** Medicare does not cover the services of a medical social worker to complete or assist in the completion of an application for Medicaid because Federal regulations require the State to provide assistance in completing the application to anyone who chooses to apply for Medicaid.);
4. **Counseling services** that are required by the patient; and
5. **Medical social services** furnished to the patient's family member or caregiver on a short-term basis when the hospice can demonstrate that a brief intervention (that is, two or three visits) by a **medical social worker** is necessary to remove a clear and direct impediment to the effective treatment of the patient's medical condition or to the patient's rate of recovery. To be considered "clear and direct," the behavior or actions of the family member or caregiver must plainly obstruct, contravene, or prevent the patient's medical treatment or rate of recovery. **Medical social services** to address general problems that do not clearly and directly impede treatment or recovery as well as long-term social services furnished to family members, such as ongoing alcohol counseling, are not covered.

.....
40.1.4 - Counseling Services

(Rev. 1, 10-01-03)

A3-3143.1.D, HO-230.1.D

Counseling services are provided to the terminally ill individual and the family members or other persons caring for the individual at home. Counseling, including dietary counseling, may be provided both for the purpose of training the individual's family or other caregiver to provide care, and for the purpose of helping the individual and those caring for the individual

to adjust to the individual's approaching death. Also, see §40.4 regarding waivers under certain conditions for making dietary counseling available.

.....

40.2.3 - Bereavement Counseling

(Rev. 1, 10-01-03)

A3-3143.2.C, HO-230.3.C

Bereavement counseling consists of counseling services provided to the individual's family after the individual's death. Bereavement counseling is a required hospice service, provided for a period up to one year following the patients' death. It is not separately reimbursable.

Bereavement specifics are found in State Operations Manual, Appendix M, CFR 418.88, L199 and L200.

MEDICARE PART B
(Supplementary Medical Insurance Benefits)

OUTPATIENT MENTAL HEALTH – CLINICAL SOCIAL WORK SERVICES/CLINICAL SOCIAL WORKER

With the passage of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89) (P.L. 101-239), the Social Security Act was amended to provide coverage of clinical social workers under Medicare Part B, effective July 1, 1990.

Section 6113(b) of OBRA '89 provides for reimbursement to clinical social workers. Specifically, Section 1861(s)(2) of the Social Security Act is amended to include coverage of clinical social worker services under "Medical and Other Health Services." Section 1861(hh)(1) of the statute defines *clinical social worker* as an individual who must have a master's or doctoral degree in social work, at least two years of supervised clinical social work practice, and be licensed or certified as a clinical social worker in the state in which the services are being performed. In the states that do not provide for licensure or certification, the individual must have completed two years or 3,000 hours of post-master's supervised clinical social work in an appropriate setting, and meet other criteria established by the Secretary of the U.S. Department of Health and Human Services.

In accordance with the OBRA '89 amendment, Section 1861(hh)(2) defines "clinical social worker services" as services related to the diagnosis and treatment of mental illnesses that the clinical social worker is legally authorized to perform under state law and those that would otherwise be covered if furnished by a physician or as an incident to a physician's professional service. The OBRA '89 language excludes coverage for clinical social worker services furnished to an inpatient of a hospital or skilled nursing facility in which the facility is required to provide such services as a condition of participation under Medicare. NASW is working to rectify this inequity through legislative changes.

With respect to reimbursement, the OBRA '89 amendment states that payment to clinical social workers shall be 80 percent of the lesser of the actual charge for the services or 75 percent of the amount determined for payment to a psychologist.

In addition, there continues to be a statutory limit on the payment for the treatment of mental, psychoneurotic, and personality disorders on an outpatient basis in a calendar year. This limitation does not apply to diagnostic services. OBRA '89 eliminated any cap in terms of a set dollar amount effective January 1, 1990, but continued the provision that limits payment to 62.5 percent of expenses. Medicare Part B pays only 80 percent of covered costs with the beneficiary required to pay a 20 percent co-payment. The 62.5 percent applies to the overall expenses, which results in the beneficiary paying what amounts to a 50 percent co-payment. Because the new law also requires that clinical social workers and psychologists accept Medicare assignment, they cannot ask the beneficiary to pay the difference between their normal service charge and the fee schedule amount approved by Medicare.

Section 4106 of OBRA '90 also imposes additional limitations on payment to "new physicians and other new health care practitioners," which includes clinical social workers. This provision limits reimbursement under Part B of Medicare to 80 percent of the prevailing charge or fee schedule for the first year of practice, 85 percent for the second year, 90 percent for the third year, and 95 percent for the fourth year. The Health Care Financing Administration (HCFA) interpreted "year of practice" as tied to participation in Medicare, rather than years of experience as a health care practitioner.

Section 6113(c) of OBRA '89 requires that qualified psychologists, in order to receive reimbursement under Medicare Part B, agree to consult with a patient's attending physician. In

1994, Public Law 103-432 clarified that clinical social workers can also receive direct reimbursement if they agree to consult with the patient's attending physician.

In an outpatient setting of a hospital or a psychiatric hospital, clinical social work services can be covered under the Medicare Part B provisions. However, hospitals with social services departments will more likely use staff social workers to provide outpatient services. A discussion related to the coverage of social workers providing partial hospitalization services in the treatment of mental illness is covered in a separate section in this document.

It is important to note that payments for outpatient mental health benefits received in a hospital are not subject to the mental health payment limitations that apply to other outpatient, ambulatory settings. A clinical social worker, like many non-physician practitioners who provide services to hospital outpatients, cannot bill the patient directly. In accordance with the "bundling of services" provision of the law, clinical social workers would have to bill the hospital for services to Medicare patients.⁹

Initially, it was believed that services and supplies incident to the services of clinical social workers under the new Medicare Part B provision would also be covered, but this has subsequently been deleted from the first draft of the HCFA instructions to carriers.

Although of less significance with the inclusion of clinical social workers under Part B, social workers continue to be potentially covered as providers of therapeutic services in a variety of outpatient settings as incident to physicians' services. The Social Security statute refers to coverage under Medicare Part B of services and supplies that are incident to physicians' services as services that are commonly furnished in a physician's office or a clinic and typically without charge or as charges included as part of a physician's bill. Services incident to a physician's services "must be furnished as an integral, although incidental, part of the physician's personal professional services in the course of diagnosis or treatment."¹⁰ Furthermore, such non-physician services must be provided under a physician's direct supervision as employees of the physician. It would appear that coverage for social work services in an outpatient setting as incident to a physician's services would be particularly relevant for social workers who do not meet the definition of a clinical social worker as defined under the statute or where there has been no formal arrangements with clinical social workers, as required by certain facilities.

All relevant statutory and regulatory citations are on the following pages. Also included are all pertinent CMS instructional materials to fiscal intermediaries and carriers.

⁹ U.S. Department of Health and Human Services (1989) Provider reimbursement manual. [Online]. Retrieved from http://www.cms.hhs.gov/manuals/pub151/PUB_15_1.asp on June 7, 2005.

¹⁰ 1990 Medicare Explained. (1990). Chicago: Commerce Clearing House, Inc.

Omnibus Budget Reconciliation Act of 1989

P.L. 101-239

SEC. 6113. MENTAL HEALTH SERVICES.

(a) ELIMINATING RESTRICTION ON PSYCHOLOGISTS' SERVICES TO SERVICES FURNISHED AT COMMUNITY MENTAL HEALTH CENTERS- Section 1861(ii) of the Social Security Act (42 U.S.C. 1395x(ii)) is amended by striking 'on-site at a community mental health center' and all that follows through 'because of similar circumstances of the individual,'.

(b) CLINICAL SOCIAL WORKERS-

(1) COVERAGE OF SERVICES- Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2)) is amended--

(A) by striking 'and' at the end of subparagraph (L);

(B) by adding 'and' at the end of subparagraph (M); and

(C) by adding at the end the following new subparagraph:

'(N) clinical social worker services (as defined in subsection (hh)(2));'.

(2) DEFINITIONS- Section 1861 of such Act (42 U.S.C. 1395x) is amended--

(A) in subsection (s)(2)(H)(ii), by striking '(hh)' and inserting '(hh)(2)', and

(B) in subsection (hh)--

(i) by amending the heading to read as follows:

'Clinical Social Worker; Clinical Social Worker Services',

(ii) by redesignating clauses (i) and (ii) of paragraph (3)(B) as subclauses (I) and (II), respectively,

(iii) by redesignating subparagraphs (A) and (B) of paragraph (3) as clauses (i) and (ii), respectively,

(iv) by redesignating paragraphs (1), (2), and (3) as subparagraphs (A), (B), and (C), respectively,

(v) by striking '(hh)' and inserting '(hh)(1)', and

(vi) by adding at the end the following new paragraph:

'(2) The term 'clinical social worker services' means services performed by a clinical social worker (as defined in paragraph (1)) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital and other than services furnished to an inpatient of a skilled nursing facility which the facility is required to provide as a requirement for participation) which the clinical social worker is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are performed as would otherwise be covered if furnished by a physician or as an incident to a physician's professional service.'

(3) PAYMENT BASIS- Section 1833 of such Act (42 U.S.C. 1395l) is amended--

(A) by inserting after clause (E) of subsection (a)(1) the following new clause: '(F) with respect to clinical social worker services under section 1861(s)(2)(N), the amounts paid shall be 80 percent of the lesser of (i) the actual charge for the services or (ii) 75 percent of the amount determined for payment of a psychologist under clause (L);' and

(B) in subsection (p)--

(i) by striking '1861(s)(2)(L) and' and by inserting '1861(s)(2)(L)', and

(ii) by inserting 'and in the case of clinical social worker services for which payment may be made under this part only pursuant to section 1861(s)(2)(N),' after '1861(s)(2)(M)',.

(c) DEVELOPMENT OF CRITERIA REGARDING CONSULTATION WITH A PHYSICIAN- The Secretary of Health and Human Services shall, taking into consideration concerns for patient confidentiality, develop criteria with respect to payment for qualified psychologist services for which payment may be made directly to the psychologist under part B of title XVIII of the Social Security Act under which such a psychologist must agree to consult with a patient's attending physician in accordance with such criteria.

(d) ELIMINATING DOLLAR LIMITATION ON MENTAL HEALTH SERVICES- Section 1833(d)(1) of the Social Security Act (42 U.S.C. 1395l(d)(1)) is amended by striking 'whichever' and all that follows in the first sentence and inserting '62 1/2 percent of such expenses.'.

(e) EFFECTIVE DATE- The amendments made by this section, and the provisions of subsection (c), shall apply to services furnished on or after July 1, 1990, and the amendments made by subsection (d) shall apply to expenses incurred in a year beginning with 1990.

Omnibus Budget Reconciliation Act of 1990
P.L. 101-508

SEC. 4106. NEW PHYSICIANS AND OTHER NEW HEALTH CARE PRACTITIONERS.

(a) EXTENSION OF CUSTOMARY CHARGE LIMIT AND INCLUSION OF HEALTH CARE PRACTITIONERS-

(1) IN GENERAL- Subparagraph (F) of section 1842(b)(4) (42 U.S.C. 1395u(b)(4)) is amended to read as follows:

`(F)(i) In the case of physicians' services and professional services of a health care practitioner (other than primary care services and other than services furnished in a rural area (as defined in section 1886(d)(2)(D)) that is designated, under section 332(a)(1)(A) of the Public Health Service Act, as a health manpower shortage area) furnished during the physician's or practitioner's first through fourth years of practice (if payment for those services is made separately under this part and on other than a cost-related basis), the prevailing charge or fee schedule amount to be applied under this part shall be 80 percent for the first year of practice, 85 percent for the second year of practice, 90 percent for the third year of practice, and 95 percent for the fourth year of practice, of the prevailing charge or fee schedule amount for that service under the other provisions of this part.

`(ii) For purposes of clause (i):

`(I) The term `health care practitioner' means a physician assistant, certified nurse-midwife, qualified psychologist, nurse practitioner, **clinical social worker**, physical therapist, occupational therapist, respiratory therapist, certified registered nurse anesthetist, or any other practitioner as may be specified by the Secretary.

`(II) The term `first year of practice' means, with respect to a physician or practitioner, the first calendar year during the first 6 months of which the physician or practitioner furnishes professional services for which payment is made under this part, and includes any period before such year.

`(III) The terms `second year of practice', `third year of practice', and `fourth year of practice' mean the second, third, and fourth calendar years, respectively, following the first year of practice.'.

SOCIAL SECURITY ACT § 1833

42USC1395I

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part B--Supplementary Medical Insurance Benefits for Aged and Disabled

Sec. 1395I. Payment of benefits

(a) Amounts

Except as provided in section 1395mm of this title, and subject to the succeeding provisions of this section, there shall be paid from the Federal Supplementary Medical Insurance Trust Fund, in the case of each individual who is covered under the insurance program established by this part and incurs expenses for services with respect to which benefits are payable under this part, amounts equal to--

(1) in the case of services described in section 1395k(a)(1) of this title--80 percent of the reasonable charges for the services; except that (A) an organization which provides medical and other health services (or arranges for their availability) on a prepayment basis (and either is sponsored by a union or employer, or does not provide, or arrange for the provision of, any inpatient hospital services) may elect to be paid 80 percent of the reasonable cost of services for which payment may be made under this part on behalf of individuals enrolled in such organization in lieu of 80 percent of the reasonable charges for such services if the organization undertakes to charge such individuals no more than 20 percent of such reasonable cost plus any amounts payable by them as a result of subsection (b) of this section, (B) with respect to items and services described in section 1395x(s)(10)(A) of this title, the amounts paid shall be 100 percent of the reasonable charges for such items and services, (C) with respect to expenses incurred for those physicians' services for which payment may be made under this part that are described in section 1395y(a)(4) of this title, the amounts paid shall be subject to such limitations as may be prescribed by regulations, (D) with respect to clinical diagnostic laboratory tests for which payment is made under this part (i) on the basis of a fee schedule under subsection (h)(1) of this section or section 1395m(d)(1) of this title, the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis or which are furnished on an outpatient basis by a critical access hospital) of the lesser of the amount determined under such fee schedule, the limitation amount for that test determined under subsection (h)(4)(B) of this section, or the amount of the charges billed for the tests, or (ii) on the basis of a negotiated rate established under subsection (h)(6) of this section, the amount paid shall be equal to 100 percent of such negotiated rate, (E) with respect to services furnished to individuals who have been determined to have end stage renal disease, the amounts paid shall be determined subject to the provisions of section 1395rr of this title, (F) with respect to **clinical social worker services** under section 1395x(s)(2)(N) of this title, the **amounts paid shall be 80 percent of the lesser of (i) the actual charge for the services or (ii) 75 percent of the amount determined for payment of a psychologist under clause (L), [(G) Repealed. Pub. L. 103-432, title I, Sec. 156(a)(2)(B)(ii), Oct. 31, 1994, 108 Stat. 4440.]** (H) with respect to services of a certified registered nurse anesthetist under section 1395x(s)(11) of this title, the amounts paid shall be 80 percent of the least of the actual charge, the prevailing charge that would be recognized (or, for services furnished on or after January 1, 1992, the fee schedule amount provided under

section 1395w-4 of this title) if the services had been performed by an anesthesiologist, or the fee schedule for such services established by the Secretary in accordance with subsection (I) of this section, (I) with respect to covered items (described in section 1395m(a)(13) of this title), the amounts paid shall be the amounts described in section 1395m(a)(1) of this title, and (J) with respect to expenses incurred for radiologist services (as defined in section 1395m(b)(6) of this title), subject to section 1395w-4 of this title, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount provided under the fee schedule established under section 1395m(b) of this title, (K) with respect to certified nurse-midwife services under section 1395x(s)(2)(L) of this title, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph (but in no event shall such fee schedule exceed 65 percent of the prevailing charge that would be allowed for the same service performed by a physician, or, for services furnished on or after January 1, 1992, 65 percent of the fee schedule amount provided under section 1395w-4 of this title for the same service performed by a physician), (L) with respect to qualified psychologist services under section 1395x(s)(2)(M) of this title, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph, (M) with respect to prosthetic devices and orthotics and prosthetics (as defined in section 1395m(h)(4) of this title), the amounts paid shall be the amounts described in section 1395m(h)(1) of this title,

.....
(c) Mental disorders

Notwithstanding any other provision of this part, with respect to expenses incurred in any calendar year in connection with the **treatment of mental, psychoneurotic, and personality disorders** of an individual who is not an inpatient of a hospital at the time such expenses are incurred, there shall be considered as incurred expenses for purposes of subsections (a) and (b) of this section only 62½ percent of such expenses. For purposes of this subsection, the term "treatment" does not include brief office visits (as defined by the Secretary) for the sole purpose of monitoring or changing drug prescriptions used in the treatment of such disorders or partial hospitalization services that are not directly provided by a physician.

d) Nonduplication of payments

No payment may be made under this part with respect to any services furnished an individual to the extent that such individual is entitled (or would be entitled except for section 1395e of this title) to have payment made with respect to such services under part A of this subchapter.

(e) Information for determination of amounts due

No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

.....
Subsec. (p). Pub. L. 103-432, Sec. 123(b)(2)(A)(ii), struck out subsec. (p) which read as follows: "In the case of certified nurse-midwife services for which payment may be made under this part only pursuant to section 1395x(s)(2)(L) of this title, in the case of qualified psychologists services for which payment may be made under this part only pursuant to section 1395x(s)(2)(M) of this title, and in the case of **clinical social worker services** for which

payment may be made under this part only pursuant to section 1395x(s)(2)(N) of this title, payment may only be made under this part for such services on an assignment-related basis. Except for deductible and coinsurance amounts applicable under this section, whoever knowingly and willfully presents, or causes to be presented, to an individual enrolled under this part a bill or request for payment for services described in the previous sentence, is subject to a civil money penalty of not to exceed \$2,000 for each such bill or request. The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title."

.....
Subsec. (p). Pub. L. 101-239, Sec. 6113(b)(3)(B), substituted ``1395x(s)(2)(L) of this title," for ``1395x(s)(2)(L) of this title and" and inserted ``and in the case of **clinical social worker services** for which payment may be made under this part only pursuant to section 1395x(s)(2)(N) of this title," after ``section 1395x(s)(2)(M) of this title,".

.....
Development of Criteria Regarding Consultation With a Physician

Section 6113(c) of Pub. L. 101-239, as amended by Pub. L. 103-432, title I, Sec. 147(b), Oct. 31, 1994, 108 Stat. 4429, provided that: ``The Secretary of Health and Human Services shall, taking into consideration concerns for patient confidentiality, develop criteria with respect to payment for qualified psychologist services and **clinical social worker services** for which payment may be made directly to the psychologist or **clinical social worker** under part B of title XVIII of the Social Security Act [this part] under which such a psychologist or clinical social worker must agree to consult with a patient's attending physician in accordance with such criteria."

[Section 147(b) of Pub. L. 103-432 provided that the amendment made by that section to section 6113(c) of Pub. L. 101-239, set out above, is effective with respect to services furnished on or after Jan. 1, 1991.]

SOCIAL SECURITY ACT § 1842

42USC1395u

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part B--Supplementary Medical Insurance Benefits for Aged and Disabled

Sec. 1395u. Use of carriers for administration of benefits

(a) Authority of Secretary to enter into contracts with carriers

In order to provide for the administration of the benefits under this part with maximum efficiency and convenience for individuals entitled to benefits under this part and for providers of services and other persons furnishing services to such individuals, and with a view to furthering coordination of the administration of the benefits under part A of this subchapter and under this part, the Secretary is authorized to enter into contracts with carriers, including carriers with which agreements under section 1395h of this title are in effect, which will perform some or all of the following functions (or, to the extent provided in such contracts, will secure performance thereof by other organizations); and, with respect to any of the following functions which involve

payments for physicians' services on a reasonable charge basis, the Secretary shall to the extent possible enter into such contracts:

(1)(A) make determinations of the rates and amounts of payments required pursuant to this part to be made to providers of services and other persons on a reasonable cost or reasonable charge basis (as may be applicable);

(B) receive, disburse, and account for funds in making such payments; and

(C) make such audits of the records of providers of services as may be necessary to assure that proper payments are made under this part;

(2)(A) determine compliance with the requirements of section 1395x(k) of this title as to utilization review; and

(B) assist providers of services and other persons who furnish services for which payment may be made under this part in the development of procedures relating to utilization practices, make studies of the effectiveness of such procedures and methods for their improvement, assist in the application of safeguards against unnecessary utilization of services furnished by providers of services and other persons to individuals entitled to benefits under this part, and provide procedures for and assist in arranging, where necessary, the establishment of groups outside hospitals (meeting the requirements of section 1395x(k)(2) of this title) to make reviews of utilization;

(3) serve as a channel of communication of information relating to the administration of this part; and (4) otherwise assist, in such manner as the contract may provide, in discharging administrative duties necessary to carry out the purposes of this part.

.....

(18)(A) Payment for any service furnished by a practitioner described in subparagraph (C) and for which payment may be made under this part on a reasonable charge or fee schedule basis may only be made under this part on an assignment-related basis.

(B) A practitioner described in subparagraph (C) or other person may not bill (or collect any amount from) the individual or another person for any service described in subparagraph (A), except for deductible and coinsurance amounts applicable under this part. No person is liable for payment of any amounts billed for such a service in violation of the previous sentence. If a practitioner or other person knowingly and willfully bills (or collects an amount) for such a service in violation of such sentence, the Secretary may apply sanctions against the practitioner or other person in the same manner as the Secretary may apply sanctions against a physician in accordance with subsection (j)(2) of this section in the same manner as such section applies with respect to a physician. Paragraph (4) of subsection (j) of this section shall apply in this subparagraph in the same manner as such paragraph applies to such section.

(C) A practitioner described in this subparagraph is any of the following:

(i) A physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1395x(aa)(5) of this title).

(ii) A certified registered nurse anesthetist (as defined in section 1395x(bb)(2) of this title).

(iii) A certified nurse-midwife (as defined in section 1395x(gg)(2) of this title).

(iv) A **clinical social worker** (as defined in section 1395x(hh)(1) of this title).

(v) A clinical psychologist (as defined by the Secretary for purposes of section 1395x(ii) of this title).

(D) For purposes of this paragraph, a service furnished by a practitioner described in subparagraph (C) includes any services and supplies furnished as incident to the service as

would otherwise be covered under this part if furnished by a physician or as incident to a physician's service.

.....

SOCIAL SECURITY ACT § 1861

42USC1395x

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part D--Miscellaneous Provisions

Sec. 1395x. Definitions

For purposes of this subchapter--

(s) Medical and other health services

The term ``medical and other health services" means any of the following items or services:

(1) physicians' services;

(2)(A) services and supplies (including drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered) furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills;

(B) hospital services (including drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered) incident to physicians' services rendered to outpatients and partial hospitalization services incident to such services;

(C) diagnostic services which are--

(i) furnished to an individual as an outpatient by a hospital or by others under arrangements with them made by a hospital, and

(ii) ordinarily furnished by such hospital (or by others under such arrangements) to its outpatients for the purpose of diagnostic study;

(D) outpatient physical therapy services and outpatient occupational therapy services;

(E) rural health clinic services and Federally qualified health center services;

(F) home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies;

(G) antigens (subject to quantity limitations prescribed in regulations by the Secretary) prepared by a physician, as defined in subsection (r)(1) of this section, for a particular patient, including antigens so prepared which are forwarded to another qualified person (including a rural health clinic) for administration to such patient, from time to time, by or under the supervision of another such physician;

(H)(i) services furnished pursuant to a contract under section 1395mm of this title to a member of an eligible organization by a physician assistant or by a nurse practitioner (as defined in subsection (aa)(5) of this section) and such services and supplies furnished as an incident to his service to such a member as would otherwise be covered under this part if furnished by a physician or as an incident to a physician's service; and

(ii) services furnished pursuant to a risk-sharing contract under section 1395mm(g) of this title to a member of an eligible organization by a clinical psychologist (as defined by the Secretary) or by a **clinical social worker** (as defined in subsection (hh)(2) of this section), and such services and supplies furnished as an incident to such clinical psychologist's services or

clinical social worker's services to such a member as would otherwise be covered under this part if furnished by a physician or as an incident to a physician's service;

(I) blood clotting factors, for hemophilia patients competent to use such factors to control bleeding without medical or other supervision, and items related to the administration of such factors, subject to utilization controls deemed necessary by the Secretary for the efficient use of such factors;

(J) prescription drugs used in immunosuppressive therapy furnished, to an individual who receives an organ transplant for which payment is made under this subchapter, but only in the case of drugs furnished--

(i) before 1995, within 12 months after the date of the transplant procedure,
(ii) during 1995, within 18 months after the date of the transplant procedure,
(iii) during 1996, within 24 months after the date of the transplant procedure,
(iv) during 1997, within 30 months after the date of the transplant procedure, and
(v) during any year after 1997, within 36 months after the date of the transplant procedure plus such additional number of months (if any) provided under section 1395k(b) of this title;

(K)(i) services which would be physicians' services if furnished by a physician (as defined in subsection (r)(1) of this section) and which are performed by a physician assistant (as defined in subsection (aa)(5) of this section) under the supervision of a physician (as so defined) and which the physician assistant is legally authorized to perform by the State in which the services are performed, and such services and supplies furnished as incident to such services as would be covered under subparagraph (A) if furnished incident to a physician's professional service; and \1\ but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services,\2\

\1\ So in original. The word ``and" probably should not appear. -

\2\ So in original. Probably should be followed by ``and". -

(ii) services which would be physicians' services if furnished by a physician (as defined in subsection (r)(1) of this section) and which are performed by a nurse practitioner or clinical nurse specialist (as defined in subsection (aa)(5) of this section) working in collaboration (as defined in subsection (aa)(6) of this section) with a physician (as defined in subsection (r)(1) of this section) which the nurse practitioner or clinical nurse specialist is legally authorized to perform by the State in which the services are performed, and such services and supplies furnished as an incident to such services as would be covered under subparagraph (A) if furnished incident to a physician's professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services;

(L) certified nurse-midwife services;

(M) qualified psychologist services;

(N) **clinical social worker services** (as defined in subsection (hh)(2) of this section);

(hh) **Clinical social worker; clinical social worker services**

(1) The term ``**clinical social worker**" means an individual who--

(A) possesses a **master's or doctor's degree in social work**;

(B) after obtaining such degree has **performed at least 2 years of supervised clinical social work**; and

(C)(i) is **licensed or certified as a clinical social worker** by the State in which the services are performed, or

(ii) in the case of an individual in a State which does not provide for licensure or certification--

(I) **has completed at least 2 years or 3,000 hours of post-master's degree supervised clinical social work practice under the supervision of a master's level social worker** in an appropriate setting (as determined by the Secretary), and

(II) meets such other criteria as the Secretary establishes.

(2) The term ``**clinical social worker services**" means services performed by a **clinical social worker** (as defined in paragraph (1)) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital and other than services furnished to an inpatient of a skilled nursing facility which the facility is required to provide as a requirement for participation) which the **clinical social worker** is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are performed as would otherwise be covered if furnished by a physician or as an incident to a physician's professional service.

(ii) **Qualified psychologist services**

The term ``qualified psychologist services" means such services and such services and supplies furnished as an incident to his service furnished by a clinical psychologist (as defined by the Secretary) which the psychologist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) as would otherwise be covered if furnished by a physician or as an incident to a physician's service.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

Subpart B—Medical and Other Health Services

§ 410.10 Medical and other health services:

Included services.

Subject to the conditions and limitations specified in this subpart, “medical and other health services” includes the following services:

a) Physicians' services.

(b) Services and supplies furnished incident to a physician's professional services, of kinds that are commonly furnished in physicians' offices and are commonly either furnished without charge or included in the physicians' bills.

(c) Services and supplies, including partial hospitalization services, that are incident to physician services and are furnished to outpatients by or under arrangements made by a hospital or a CAH.

(d) Diagnostic services furnished to outpatients by or under arrangements made by a hospital or a CAH if the services are services that the hospital or CAH ordinarily furnishes to its outpatients for diagnostic study.

....

(w) **Clinical social worker services**, as provided in § 410.73.

(x) Services of physicians and other practitioners furnished in or at the direction of an IHS or Indian tribal hospital or clinic.

[51 FR 41339, Nov. 14, 1986, as amended at 52 FR 27765, July 23, 1987; 55 FR 22790, June 4, 1990; 55 FR 53522, Dec. 31, 1990; 56 FR 8841, Mar. 1, 1991; 56 FR 43709, Sept. 4, 1991; 57 FR 24981, June 12, 1992; 57 FR 33896, July 31, 1992; 58 FR 30668, May 26, 1993; 59 FR 26959, May 25, 1994; 59 FR 49833, Sept. 30, 1994; 60 FR 8955, Feb. 16, 1995; 63 FR 20128, Apr. 23, 1998; 66 FR 55328, Nov. 1, 2001]

.....

§ 410.26 Services and supplies incident to a physician's professional services:

Conditions.

(a) Definitions. For purposes of this section, the following definitions apply:

(1) Auxiliary personnel means any individual who is acting under the supervision of a physician (or other practitioner), regardless of whether the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner).

(2) Direct supervision means the level of supervision by the physician (or other practitioner) of auxiliary personnel as defined in Sec. 410.32(b)(3)(ii).

(3) Independent contractor means an individual (or an entity that has hired such an individual) who performs part-time or full-time work for which the individual (or the entity that has hired such an individual) receives an IRS-1099 form.

(4) Leased employment means an employment relationship that is recognized by applicable State law and that is established by two employers by a contract such that one employer hires the services of an employee of the other employer.

(5) Noninstitutional setting means all settings other than a hospital or skilled nursing facility.

(6) Practitioner means a non-physician practitioner who is authorized by the Act to receive payment for services incident to his or her own services.

(7) Services and supplies means any services or supplies (including drugs or biologicals that are not usually self-administered) that are included in section 1861(s)(2)(A) of the Act and are not specifically listed in the Act as a separate benefit included in the Medicare program.

(b) Medicare Part B pays for services and supplies incident to the service of a physician (or other practitioner).

(1) Services and supplies must be furnished in a noninstitutional setting to noninstitutional patients.

(2) Services and supplies must be an integral, though incidental, part of the service of a physician (or other practitioner) in the course of diagnosis or treatment of an injury or illness.

(3) Services and supplies must be commonly furnished without charge or included in the bill of a physician (or other practitioner).

(4) Services and supplies must be of a type that are commonly furnished in the office or clinic of a physician (or other practitioner).

(5) Services and supplies must be furnished under the direct supervision of the physician (or other practitioner). The physician (or other practitioner) directly supervising the auxiliary personnel need not be the same physician (or other practitioner) upon whose professional service the incident to service is based.

(6) Services and supplies must be furnished by the physician, practitioner with an incident to benefit, or auxiliary personnel.

(7) A physician (or other practitioner) may be an employee or an independent contractor.

(c) Limitation. Drugs and biologicals are also subject to the limitations specified in Sec. 410.29.

[51 FR 41339, Nov. 14, 1986, as amended at 66 FR 55328, Nov. 1, 2001; 67 FR 20684, Apr. 26, 2002]

§ 410.27 Outpatient hospital services and supplies incident to a physician service: Conditions.

(a) Medicare Part B pays for hospital services and supplies furnished incident to a

physician service to outpatients, including drugs and biologicals that cannot be self-administered, if—

(1) They are furnished—

(i) By or under arrangements made by a participating hospital, except in the case of an SNF resident as provided in § 411.15(p) of this chapter;

(ii) As an integral though incidental part of a physician's services; and

(iii) In the hospital or at a location (other than an RHC or an FQHC) that CMS designates as a department of a provider under § 413.65 of this chapter; and
(2) In the case of partial hospitalization services, also meet the conditions of paragraph (d) of this section.

(b) Drugs and biologicals are also subject to the limitations specified in § 410.168.

(c) Rules on emergency services furnished to outpatients by nonparticipating hospitals are specified in § 410.168.

(d) Medicare Part B pays for partial hospitalization services if they are—

(1) Prescribed by a physician who certifies and recertifies the need for the services in accordance with subpart B of part 424 of this chapter; and

(2) Furnished under a plan of treatment as required under subpart B of part 424 of this chapter.

(e) Services furnished by an entity other than the hospital are subject to the limitations specified in § 410.42(a).

(f) Services furnished at a location (other than an RHC or an FQHC) that CMS designates as a department of a provider under § 413.65 of this chapter must be under the direct supervision of a physician. “Direct supervision” means the physician must be present and on the premises of the location and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the

physician must be present in the room when the procedure is performed.

[56 FR 8841, Mar. 1, 1991, as amended at 63 FR 26307, May 12, 1998; 65 FR 18536, Apr. 7, 2000]

.....
Subpart I—Payment of SMI Benefits

SOURCE: 51 FR 41339, Nov. 14, 1986.

Redesignated at 59 FR 6577, Feb. 11, 1994.

§ 410.150 To whom payment is made.

(a) *General rules.* (1) Any SMI enrollee is, subject to the conditions, limitations, and exclusions set forth in this part and in parts 405, 416 and 424 of this chapter, entitled to have payment made as specified in paragraph (b) of this section.

(2) The services specified in paragraphs (b)(5) through (b)(14) of this section must be furnished by a facility that has in effect a provider agreement or other appropriate agreement to participate in Medicare.

(b) *Specific rules.* Subject to the conditions set forth in paragraph (a) of this section, Medicare Part B pays as follows:

(1) To the individual, or to a physician or other supplier on the individual's behalf, for medical and other health services furnished by the physician or other supplier.

(2) To a nonparticipating hospital on the individual's behalf for emergency outpatient services furnished by the hospital, in accordance with subpart G of part 424 of this chapter.

(3) To the individual, for emergency outpatient services furnished by a nonparticipating hospital, in accordance with § 424.53 of this chapter.

...
(5) To a provider on the individual's behalf for medical and other health services furnished by the provider (or by others under arrangements made with them by the provider).

(6) To a home health agency on the individual's behalf for home health services furnished by the home health agency.

(7) To a clinic, rehabilitation agency, or public health agency on the individual's behalf for outpatient physical therapy or speech pathology services furnished by the clinic or agency (or by others under arrangements made with them by the clinic or agency).

(8) To a rural health clinic or Federally qualified health center on the individual's behalf for rural health clinic or Federally qualified health center services furnished by the rural health clinic or Federally qualified health center, respectively.

...
(10) To a comprehensive outpatient rehabilitation facility (CORF) on the individual's behalf for comprehensive outpatient rehabilitation facility services furnished by the CORF.

(11) To a renal dialysis facility, on the individual's behalf, for institutional or home dialysis services, supplies, and equipment furnished by the facility.

(12) To a critical access hospital (CAH) on the individual's behalf for outpatient CAH services furnished by the CAH.

(13) To a **community mental health center** (CMHC) on the individual's behalf, for partial hospitalization services furnished by the CMHC (or by others under arrangements made with them by the CMHC).

(14) To an SNF for services (other than those described in § 411.15(p)(2) of this chapter) that it furnishes to a resident (as defined in § 411.15(p)(3) of this chapter) of the SNF who is not in a covered Part A stay.

...
(18) To a **clinical social worker** on the individual's behalf for clinical social worker services.

...
[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988; 57 FR 24981, June 12, 1992; 58 FR 30668, May 26, 1993; 59 FR 6577, Feb. 11, 1994; 63 FR 20129, Apr. 23, 1998; 63 FR 26308, May 12, 1998; 63 FR 8909, Nov. 2,

1998; 65 FR 41211, July 3, 2000; 66 FR 39599, July 31, 2001]

...

§ 410.155 Outpatient mental health treatment limitation.

(a) *Limitation.* Only 62½ percent of the expenses incurred for services subject to the limit as specified in paragraph (b) of this section are considered incurred expenses under Medicare Part B when determining the amount of payment and deductible under §§ 410.152 and 410.160, respectively.

(b) *Application of the limitation—(1)*

Services subject to the limitation. Except as specified in paragraph (b)(2) of this section, the following services are subject to the limitation if they are furnished in connection with the treatment of a mental, psychoneurotic, or personality disorder (that is, any condition identified by a diagnosis code within the range of 290 through 319) and are furnished to an individual who is not an inpatient of a hospital:

(i) Services furnished by physicians and other practitioners, whether furnished directly or as an incident to those practitioners' services.

(ii) Services provided by a CORF.

(2) *Services not subject to the limitation.*

Services not subject to the limitation include the following:

(i) Services furnished to a hospital inpatient.

(ii) Brief office visits for the sole purpose of monitoring or changing drug prescriptions used in the treatment of mental, psychoneurotic, or personality disorders.

(iii) Partial hospitalization services not directly provided by a physician.

(iv) Diagnostic services, such as psychological testing, that are performed to establish a diagnosis.

(v) Medical management, as opposed to psychotherapy, furnished to a patient diagnosed with Alzheimer's disease or a related disorder.

(c) *Examples.* (1) A clinical psychologist submitted a claim for \$200 for outpatient treatment of a beneficiary's mental disorder. The Medicare approved amount was \$180. Since clinical psychologists must accept assignment, the beneficiary is not liable for the \$20 in excess charges. The beneficiary previously satisfied the \$100 annual Part B deductible. The limitation reduces the amount of incurred expenses to 62½ percent of the approved amount. After subtracting any unmet deductible, Medicare pays 80 percent of the remaining incurred expenses. Medicare payment and beneficiary liability are computed as follows:

1. Actual charges.....	\$200.00
2. Medicare approved amount.....	180.00
3. Medicare incurred expenses (0.625 · line 2)	112.50
4. Unmet deductible	0.00
5. Remainder after subtracting deductible (line 3 minus line 4)	112.50
6. Medicare payment (0.80 · line 5)	90.00
7. Beneficiary liability (line 2 minus line 6) ..	90.00

(2) A **clinical social worker** submitted a claim for \$135 for outpatient treatment of a beneficiary's mental disorder.

The Medicare approved amount was \$120. Since clinical social workers must accept assignment, the beneficiary is not liable for the \$15 in excess charges. The beneficiary previously satisfied \$70 of the \$100 annual Part B deductible, leaving \$30 unmet.

1. Actual charges	\$135.00
2. Medicare approved amount	120.00
3. Medicare incurred expenses (0.625 · line 2)	75.00
4. Unmet deductible	30.00
5. Remainder after subtracting deductible (line 3 minus line 4)	45.00
6. Medicare payment (0.80 · line 5)	36.00
7. Beneficiary liability (line 2 minus line 6) ..	84.00

(3) A physician who did not accept assignment submitted a claim for \$780 for services in connection with the treatment of a mental disorder that did not require inpatient hospitalization. The Medicare approved amount was \$750. Because the physician did not accept assignment, the beneficiary is liable for the

\$30 in excess charges. The beneficiary had not satisfied any of the \$100

Part B annual deductible.

1. Actual charges	\$780.00
2. Medicare approved amount	750.00
3. Medicare incurred expenses (0.625 ·	
line 2)	468.75
4. Unmet deductible	100.00
5. Remainder after subtracting deductible	
(line 3 minus line 4)	368.75
6. Medicare payment (0.80 · line 5)	295.00
7. Beneficiary liability (line 1 minus line 6).	485.00

(4) A beneficiary's only Part B expenses during 1995 were for a physician's services in connection with the treatment of a mental disorder that initially required inpatient hospitalization.

The remaining services were furnished on an outpatient basis. The beneficiary had not satisfied any of the \$100 annual Part B deductible in 1995.

The physician, who accepted assignment, submitted a claim for \$780. The Medicare-approved amount was \$750. The beneficiary incurred \$350 of the approved amount while a hospital inpatient and incurred the remaining \$400 of the approved amount for outpatient services. Only \$400 of the approved amount is subject to the 621.2 percent limitation because the statutory limitation does not apply to services furnished to hospital inpatients.

1. Actual charges	\$780.00
2. Medicare approved amount	\$750.00
2A. Inpatient portion	\$350
2B. Outpatient portion	\$400
3. Medicare incurred expenses	\$600.00
3A. Inpatient portion	\$350
3B. Outpatient portion (0.625 · line 2B) ...	\$250
4. Unmet deductible	\$100.00
5. Remainder after subtracting deductible	
(line 3 minus line 4)	\$500.00
6. Medicare payment (0.80 · line 5)	\$400.00
7. Beneficiary liability (line 2 minus line 6)	\$350.00

[63 FR 20129, Apr. 23, 1998]

...

§ 410.172 Payment for partial hospitalization services in CMHCs: Conditions.

Medicare Part B pays for partial hospitalization services furnished in a

CMHC on behalf of an individual only if the following conditions are met:

(a) The CMHC files a written request for payment on the CMS form 1450 and in the manner prescribed by CMS; and

(b) The services are furnished in accordance with the requirements described in §410.110.

[59 FR 6578, Feb. 11, 1994]

Medicare Benefit Policy Manual
CHAPTER 6 - HOSPITAL SERVICES COVERED UNDER PART B

70 - Outpatient Hospital Psychiatric Services

(Rev. 1, 10-01-03)

A3-3112.7, HO-230.5

70.1 - General

(Rev. 10, 05-07-04)

A3-3112.7.A, HO-230.5.A

There is a wide range of services and programs that a hospital may provide to its outpatients who need psychiatric care, ranging from a few individual services to comprehensive, full-day programs; from intensive treatment programs to those that provide primarily supportive.

In general, to be covered the services must be:

- Incident to a physician's service (see §20.4); and
- Reasonable and necessary for the diagnosis or treatment of the patient's condition.

This means the services must be for the purpose of diagnostic study or the services must reasonably be expected to improve the patient's condition.

A. Coverage Criteria.--The services must meet the following criteria:

1. Individualized Treatment Plan.--Services must be prescribed by a physician and provided under an individualized written plan of treatment established by a physician after any needed consultation with appropriate staff members. The plan must state the type, amount, frequency, and duration of the services to be furnished and indicate the diagnoses and anticipated goals. (A plan is not required if only a few brief services are furnished.)

2. Physician Supervision and Evaluation.--Services must be supervised and periodically evaluated by a physician to determine the extent to which treatment goals are being realized. The evaluation must be based on periodic consultation and conference with therapists and staff, review of medical records, and patient interviews. Physician entries in medical records must support this involvement. The physician must also provide supervision and direction to any therapist involved in the patient's treatment and see the patient periodically to evaluate the course of treatment and to determine the extent to which treatment goals are being realized and whether changes in direction or emphasis are needed.

3. Reasonable Expectation of Improvement.--Services must be for the purpose of diagnostic study or reasonably be expected to improve the patient's condition. The treatment must, at a

minimum, be designed to reduce or control the patient's psychiatric symptoms so as to prevent relapse or hospitalization, and improve or maintain the patient's level of functioning.

It is not necessary that a course of therapy have as its goal restoration of the patient to the level of functioning exhibited prior to the onset of the illness, although this may be appropriate for some patients. For many other psychiatric patients, particularly those with long-term, chronic conditions, control of symptoms and maintenance of a functional level to avoid further deterioration or hospitalization is an acceptable expectation of improvement. "Improvement" in this context is measured by comparing the effect of continuing treatment versus discontinuing it. Where there is a reasonable expectation that if treatment services were withdrawn the patient's condition would deteriorate, relapse further, or require hospitalization, this criterion is met.

Some patients may undergo a course of treatment that increases their level of functioning, but then reach a point where further significant increase is not expected. Such claims are not automatically considered noncovered because conditions have stabilized, or because treatment is now primarily for the purpose of maintaining present level of functioning. Rather, coverage depends on whether the criteria discussed above are met. Services are noncovered only where the evidence clearly establishes that the criteria are not met; for example, that stability can be maintained without further treatment or with less intensive treatment.

B Partial Hospitalization.--Partial hospitalization is a distinct and organized intensive treatment program for patients who would otherwise require inpatient psychiatric care. See §70.3 for specific program requirements.

C. Application of Criteria.-- The following discussion illustrates the application of above guidelines to the more common modalities and procedures used in the treatment of psychiatric patients and some factors that are considered in determining whether the coverage criteria are met.

1. Covered Services.--Services generally covered for the treatment of psychiatric patients are:

- Individual and group therapy with physicians, psychologists, or other mental health professionals authorized by the State.*
- Occupational therapy services are covered if they require the skills of a qualified occupational therapist and be performed by or under the supervision of a qualified occupational therapist or by an occupational therapy assistant.*
- Services of **social workers**, trained psychiatric nurses, and other staff, trained psychiatric nurses, and other staff trained to work with psychiatric patients.*
- Drugs and biologicals furnished to outpatients for therapeutic purposes, but only if they are of a type which cannot be self-administered.*
- Activity therapies but only those that are individualized and essential for the treatment of the patient's condition. The treatment plan must clearly justify the*

need for each particular therapy utilized and explain how it fits into the patient's treatment.

- *Family counseling services. Counseling services with members of the household are covered only where the primary purpose of such counseling is the treatment of the patient's condition.*
- *Patient education programs, but only where the educational activities are closely related to the care and treatment of the patient.*
- *Diagnostic services for the purpose of diagnosing those individuals for whom an extended or direct observation is necessary to determine functioning and interactions, to identify problem areas, and to formulate a treatment plan.*

2. Noncovered Services.--The following are generally not covered except as indicated:

- *Meals and transportation.*
- *Activity therapies, group activities or other services and programs which are primarily recreational or diversional in nature. Outpatient psychiatric day treatment programs that consist entirely of activity therapies are not covered.*

"Geriatric day care" programs are available in both medical and nonmedical settings. They provide social and recreational activities to older individuals who need some supervision during the day while other family members are away from home. Such programs are not covered since they are not considered reasonable and necessary for a diagnosed psychiatric disorder, nor do such programs routinely have physician involvement.

3.

- *Psychosocial programs. These are generally community support groups in nonmedical settings for chronically mentally ill persons for the purpose of social interaction. Outpatient programs may include some psychosocial components; and to the extent these components are not primarily for social or recreational purposes, they are covered. However, if an individual's outpatient hospital program consists entirely of psychosocial activities, it is not covered.*
- *Vocational training. While occupational therapy may include vocational and prevocational assessment and training, when the services are related solely to specific employment opportunities, work skills or work settings, they are not covered.*

4. Frequency and Duration of Services.--There are no specific limits on the length of time that services may be covered. There are many factors that affect the outcome of treatment; among them are the nature of the illness, prior history, the goals of treatment, and the patient's response. As long as the evidence shows that the patient continues to show improvement in

accordance with his/her individualized treatment plan, and the frequency of services is within accepted norms of medical practice, coverage may be continued.

If a patient reaches a point in his/her treatment where further improvement does not appear to be indicated, evaluate the case in terms of the criteria to determine whether with continued treatment there is a reasonable expectation of improvement.

Provider Reimbursement Manual Part I

06-89

PROSPECTIVE PAYMENTS

2830.31

2830. PAYMENT FOR HOSPITAL OUTPATIENT SERVICES

2830.1 General.--Section 9343 of the Omnibus Budget Reconciliation Act of 1986 (Public Law 99-509) contains a number of provisions that have an impact on payments to hospitals for outpatient services. Section 9343(a) imposes a new payment methodology for certain ambulatory surgical procedures performed on an outpatient basis by hospitals. Section 9343(c) prevents unbundling of services furnished to hospital outpatients by requiring that hospitals furnish services to its Medicare patients either directly or under arrangements. Section 9343(f) requires that the Secretary develop designs and models for a prospective payment system for ambulatory surgery performed by hospitals on an outpatient basis by 1989 and to develop designs and models for a prospective payment system for other hospital outpatient services by 1991. Section 9343(g) requires hospitals to report claims for outpatient services using a HCFA Common Procedure Coding System. These provisions serve as the basis for a change in program payment for hospital outpatient services from a cost-based system to a prospective payment system.

Section 4066 of the Omnibus Budget Reconciliation Act of 1987 (Public Law 100-203) establishes a new payment methodology for hospital outpatient radiology services furnished on or after October 1, 1988 and other diagnostic procedures performed by hospitals on an outpatient basis on or after October 1, 1989.

2830.2 Bundling of Services Furnished to Hospital Outpatients.--Effective for services furnished on or after July 1, 1987, all hospitals must agree to furnish either directly or under arrangements (as described in '1861(w)(1) of the Act) all items and nonphysician services received by Medicare patients that can be covered as hospital outpatient services when these services are (1) furnished during an encounter with a patient registered by the hospital as an outpatient, or (2) diagnostic procedures or tests (e.g., magnetic resonance imaging (MRI) procedures) furnished outside the hospital but ordered during or as a result of an encounter with an outpatient, if the results of the procedure or test must be returned to the hospital for evaluation. Bundling is required not only for diagnostic and therapeutic services furnished during such an encounter, but also for prosthetic devices (e.g., intraocular lenses (IOLs) implanted or fitted during an encounter in the hospital).

Ambulance service to or from a patient's residence is not subject to the bundling requirement. However, bundling is required for transportation of patients by ambulance or other vehicle regularly used between the hospital and a diagnostic testing site for a test that is bundled.

An encounter is defined as a direct personal exchange, for the purpose of seeking care and rendering health care services, between a patient, who is not an inpatient, and a physician or other practitioner operating within hospital staff bylaws and State licensure law.

The services of certified registered nurse anesthetists (CRNAs) employed by a physician as described in 42 CFR 405.553(b)(4) are not required to be furnished directly or under arrangements by a hospital. If the physician's practice has been to employ CRNAs and bill their services under Part B on a reasonable charge basis, the physician may continue to do so for CRNA services furnished before January 1, 1989.

Allied Health Professionals/Nonphysician Practitioners**2150. CLINICAL PSYCHOLOGIST SERVICES**

Section 6113(a) of OBRA 1989 (P. L. 101-239) eliminates the restriction on clinical psychologist (CP) services imposed by prior law, which required that, to be paid for directly, the services be furnished at community mental health centers (CMHCs) or offsite at a CMHC for those who are institutionalized or are physically or mentally impaired.

A CMHC is an institution that provides the mental health services required by §1916(c)(4) of the PHS Act and is certified by the appropriate State authorities as meeting such requirements. Services furnished by a CP and services furnished incident to the services of a CP to hospital patients during the period July 1, 1990, through December 31, 1990, were bundled. Therefore, Medicare made payment to the hospital for these services. However, as a result of the enactment of §4157 of OBRA 1990, effective January 1, 1991, professional CP services furnished to hospital patients are no longer bundled under 42 CFR 411.15(m). Section 4157 amended §1862(a)(14) of the Act to permit direct payment to CPs under Medicare Part B for such services. However, services furnished incident to the professional services of CPs to hospital patients remain bundled. Therefore, payment must continue to be made to the hospital for such "incident to" services.

The diagnostic services of psychologists who are not clinical psychologists, and who are practicing independently, are discussed in §2070.2.

A. Clinical Psychologist Defined.--To qualify as a CP, a practitioner must meet the following requirements:

- Hold a doctoral degree in psychology;
- Be licensed or certified, on the basis of the doctoral degree in psychology, by the State in which he or she practices, at the independent practice level of psychology to furnish diagnostic, assessment, preventive, and therapeutic services directly to individuals.

B. Qualified Clinical Psychologist Services Defined.--Effective July 1, 1990, the diagnostic and therapeutic services of CPs and services and supplies furnished incident to such services are covered as the services furnished by a physician or as incident to physician's services are covered. However, the CP must be legally authorized to perform the services under applicable licensure laws of the State in which they are furnished.

C. Types of Clinical Psychologist Services That May Be Covered.--CPs may provide the following services:

- o Diagnostic and therapeutic services that the CP is legally authorized to perform in accordance with State law and/or regulation. Pay all qualified CPs based on the fee schedule for their diagnostic and therapeutic services. Also, pay those practitioners who do not meet the requirements for a CP on the basis of the physician fee schedule for the provision of diagnostic services under §2070.2.

o Services and supplies furnished incident to a CP's services are covered if the requirements that apply to services incident to a physician's services, as described in §2050.1 are met. These services must be:

- Mental health services that are commonly furnished in CPs' offices;
- An integral, although incidental, part of professional services performed by the CP;
- Performed under the direct personal supervision of the CP, i.e., the CP must be physically present and immediately available; and
- Furnished without charge or included in the CP's bill.

Any person involved in performing the service must be an employee of the CP (or an employee of the legal entity that employs the supervising CP) under the common law control test of the Act, as set forth in 20 CFR 404.1007 and §RS 2101.020 of the Retirement and Survivors Insurance part of the Social Security Program Operations Manual System. Be familiar with appropriate State laws and/or regulations governing a CP's scope of practice. The development of lists of appropriate services may prove useful.

D. Noncovered Services.--The services of CPs are not covered if they are otherwise excluded from Medicare coverage even though a clinical psychologist is authorized by State law to perform them. For example, §1862(a)(1)(A) of the Act excludes from coverage services that are not "reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member." Therefore, even though the services are authorized by State law, the services of a CP that are determined to be not reasonable and necessary are not covered. Additionally, any therapeutic services that are billed by CPs under CPT psychotherapy codes that include medical evaluation and management services are not covered.

E. Requirement for Consultation.--When applying for a Medicare provider number, a CP must submit to the carrier a signed Medicare provider/supplier enrollment form that indicates an agreement to the effect that, contingent upon the patient's consent, he or she will attempt to consult with the patient's attending or primary care physician in accordance with accepted professional ethical norms, taking into consideration patient confidentiality.

If the patient assents to the consultation, the CP must attempt to consult with the patient's physician within a reasonable time after receiving the consent. If the CP's attempts to consult directly with the physician are not successful, the CP must notify the physician within a reasonable time that he or she is furnishing services to the patient. Additionally, the CP must document, in the patient's medical record, the date the patient consented or declined consent to consultations, the date of consultation, or, if attempts to consult did not succeed, that date and manner of notification to the physician.

The only exception to the consultation requirement for CPs is in cases where the patient's primary care or attending physician refers the patient to the CP. Also, neither a CP nor a primary care or attending physician may bill Medicare or the patient for this required consultation. See H.R. Conf. Rep. No. 386, 101st Cong., 1st Sess. 789 (1989).

F. Payment Methodology Limitation.--Payment for the services of CPs is made on the basis of a fee schedule or the actual charge, whichever is less, and only on the basis of assignment.

G. Outpatient Mental Health Services Limitation.--All covered therapeutic services furnished by qualified CPs are subject to the outpatient mental health services limitation in §2470ff (i.e., only 62 ½ percent of expenses for these services are considered incurred expenses for Medicare purposes). The limitation does not apply to diagnostic services. (See §2472.4.C.)

H. Assignment Requirement.--Make all claims for covered services rendered by CPs on an assignment basis.

2152. CLINICAL SOCIAL WORKER SERVICES

Medical and other health services include the services provided by a **clinical social worker** (CSW). Payment is made only under assignment. The amount payable cannot exceed 80 percent of the lesser of the actual charge for the services or 75 percent of the amount paid to a psychologist for the same service. See §5112 for the payment guidelines and subsection F for application of the mental health payment limitation.

A. Clinical Social Worker Defined.--Section 1861(hh) of the Act defines a “clinical social worker” as an individual who:

- o Possesses a master’s or doctor’s degree in social work;
- o Has performed at least 2 years of supervised clinical social work; and
- o Either;
 - Is licensed or certified as a clinical social worker by the State in which the services are performed; or
 - In the case of an individual in a State that does not provide for licensure or certification, has completed at least 2 years or 3,000 hours of post master’s degree supervised clinical social work practice under the supervision of a master’s level social worker in an appropriate setting such as a hospital, SNF, or clinic.

B. Clinical Social Worker Services Defined.--Section 1861(hh)(2) of the Act defines "clinical social worker services" as those services that the CSW is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are performed for the diagnosis and treatment of mental illnesses. Services furnished to an inpatient of a hospital or an inpatient of a SNF that the SNF is required to provide as a requirement for participation are not included. The services that are covered are those that are otherwise covered if furnished by a physician or as an incident to a physician's professional service.

C. Covered Services.--Coverage is limited to the services a CSW is legally authorized to perform in accordance with State law (or State regulatory mechanism established by State law). The services of a CSW may be covered under Part B if they are:

- o The type of services that are otherwise covered if furnished by a physician, or as incident to a physician's service. (See §2020 for a description of physicians' services and §2020.2 for the definition of a physician.);
- o Performed by a person who meets the definition of a CSW (see subsection A); and
- o Not otherwise excluded from coverage.

Become familiar with the State law or regulatory mechanism governing a CSW's scope of practice in your service area. The development of a list of services within the scope of practice may prove useful.

D. Noncovered Services.--Services of a CSW are not covered when furnished to inpatients of a hospital or to inpatients of a SNF if the services furnished in the SNF are those that the SNF is required to furnish as a condition of participation in Medicare. In addition, CSW services are not covered if they are otherwise excluded from Medicare coverage even though a CSW is authorized by State law to perform them. For example, the Medicare law excludes from coverage services that are not "reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member."

F. Outpatient Mental Health Services Limitation.--All covered therapeutic services furnished by qualified CSWs are subject to the outpatient psychiatric services limitation in §2470ff (i.e., only 62 ½ percent of expenses for these services are considered incurred expenses for Medicare purposes). The limitation does not apply to diagnostic services. (See §2476.5.)

Medicare Claims Processing Manual
CHAPTER 12 - PHYSICIANS/NONPHYSICIAN PRACTITIONERS

150 - Clinical Social Worker (CSW) Services

(Rev. 1, 10-01-03)

B3-2152, B3-17000

See Medicare Benefit Policy Manual, Chapter 15, for coverage requirements.

Assignment of benefits is required.

Payment is at 75 percent of the physician fee schedule.

CSWs are identified on the provider file by specialty code 80 and provider type 56.

Medicare applies the outpatient mental health limitation to all covered therapeutic services furnished by qualified CSWs. Refer to [§210](#), below, for a discussion of the outpatient mental health limitation. The modifier “AJ” must be applied on CSN services.

...

210 - Outpatient Mental Health Limitation

(Rev. 1, 10-01-03)

B3-2470

Regardless of the actual expenses a beneficiary incurs for treatment of mental, psychoneurotic, and personality disorders while the beneficiary is not an inpatient of a hospital at the time such expenses are incurred, the amount of those expenses that may be recognized for Part B deductible and payment purposes is limited to 62.5 percent of the Medicare allowed amount for those services. This limitation is called the outpatient mental health treatment limitation. Expenses for diagnostic services (e.g., psychiatric testing and evaluation to diagnose the patient's illness) are not subject to this limitation. This limitation applies only to therapeutic services and to services performed to evaluate the progress of a course of treatment for a diagnosed condition.

COMPREHENSIVE OUTPATIENT REHABILITATION FACILITY SERVICES

SOCIAL SERVICES/SOCIAL WORKER

A comprehensive outpatient rehabilitation facility (CORF) is a public or private institution that is primarily engaged in providing (by or under the supervision of physicians) diagnostic, therapeutic, and restorative services on an outpatient basis for the rehabilitation of injured, disabled, or sick people. At a minimum, a CORF must by statute provide physicians' services, physical therapy services, and social or psychological services in accordance with a treatment plan. In addition, every patient must be under the care of a physician. (See the statutory citation, Section 1861(cc).)

The regulations (42 CFR 410.100(h)) describe social services as the following: (1) an assessment of social and emotional factors related to an individual's illness, need for care, response to treatment, and adjustment to care; (2) casework services to assist in resolving social or emotional problems that impede the individual's ability to respond to treatment; and (3) an assessment of an individual's needs on discharge, taking into consideration the patient's home situation and financial and community resources.

The regulations governing CORFs require that social workers be licensed by the state in which they are practicing, and that they have at least a bachelor's degree in social work and one year of social work experience in a health care setting.

In addition, the regulations (42 CFR 410.100(m)) provide for a single home visit to evaluate the potential impact of the home situation on the rehabilitation goals.

For situations in which CORFs provide physician and non-physician services that are for the treatment of a mental, psychoneurotic, or personality disorder, those services will be subject to the outpatient mental health payment limit. (See "Outpatient Mental Health Services" for further information on payment limit, including the relevant regulatory citations.)

SOCIAL SECURITY ACT § 1861

42USC1395x

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part D--Miscellaneous Provisions

Sec. 1395x. Definitions

For purposes of this subchapter--

.....

(cc) Comprehensive outpatient rehabilitation facility services

(1) The term ``comprehensive outpatient rehabilitation facility services" means the following items and services furnished by a physician or other qualified professional personnel (as defined in regulations by the Secretary) to an individual who is an outpatient of a comprehensive outpatient rehabilitation facility under a plan (for furnishing such items and services to such individual) established and periodically reviewed by a physician--

(A) physicians' services;

(B) physical therapy, occupational therapy, speech-language pathology services, and respiratory therapy;

(C) prosthetic and orthotic devices, including testing, fitting, or training in the use of prosthetic and orthotic devices;

(D) **social and psychological services;**

(E) nursing care provided by or under the supervision of a registered professional nurse;

(F) drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered;

(G) supplies and durable medical equipment; and

(H) such other items and services as are medically necessary for the rehabilitation of the patient and are ordinarily furnished by comprehensive outpatient rehabilitation facilities, excluding, however, any item or service if it would not be included under subsection (b) of this section if furnished to an inpatient of a hospital. In the case of physical therapy, occupational therapy, and speech pathology services, there shall be no requirement that the item or service be furnished at any single fixed location if the item or service is furnished pursuant to such plan and payments are not otherwise made for the item or service under this subchapter.

(2) The term ``comprehensive outpatient rehabilitation facility" means a facility which--

(A) is primarily engaged in providing (by or under the supervision of physicians) diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons;

(B) provides at least the following comprehensive outpatient rehabilitation services: (i) physicians' services (rendered by physicians, as defined in subsection (r)(1) of this section, who are available at the facility on a full- or part-time basis); (ii) physical therapy; and (iii) **social or psychological services;**

(C) maintains clinical records on all patients;

(D) has policies established by a group of professional personnel (associated with the facility), including one or more physicians defined in subsection (r)(1) of this section to govern the comprehensive outpatient rehabilitation services it furnishes, and provides for

the carrying out of such policies by a full- or part-time physician referred to in subparagraph (B)(i);

(E) has a requirement that every patient must be under the care of a physician;

(F) in the case of a facility in any State in which State or applicable local law provides for the licensing of facilities of this nature (i) is licensed pursuant to such law, or (ii) is approved by the agency of such State or locality, responsible for licensing facilities of this nature, as meeting the standards established for such licensing;

(G) has in effect a utilization review plan in accordance with regulations prescribed by the Secretary;

(H) has in effect an overall plan and budget that meets the requirements of subsection (z) of this section;

(I) provides the Secretary on a continuing basis with a surety bond in a form specified by the Secretary and in an amount that is not less than \$50,000; and

(J) meets such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such facility, including conditions concerning qualifications of personnel in these facilities.

The Secretary may waive the requirement of a surety bond under subparagraph (I) in the case of a facility that provides a comparable surety bond under State law.

PART 410 – SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

Subpart D—Comprehensive Outpatient Rehabilitation Facility

(CORF) Services

§ 410.100 Included services.

Subject to the conditions and limitations set forth in §§ 410.102 and 410.105, CORF services means the following services furnished to an outpatient of the CORF by personnel that meet the qualifications set forth in § 485.70 of this chapter.

...

(h) *Social services*. These services include

-
- (1) Assessment of the social and emotional factors related to the individual's illness, need for care, response to treatment, and adjustment to care furnished by the facility;
- (2) Casework services to assist in resolving social or emotional problems that may have an adverse effect on the beneficiary's ability to respond to treatment; and
- (3) Assessment of the relationship of the individual's medical and nursing requirements to his or her home situation, financial resources, and the community resources available upon discharge from facility care.

(i) *Psychological services*. These services include—

- (1) Assessment, diagnosis and treatment of an individual's mental and emotional functioning as it relates to the individual's rehabilitation;
- (2) Psychological evaluations of the individual's response to and rate of progress under the treatment plan; and
- (3) Assessment of those aspects of an individual's family and home situation that affect the individual's rehabilitation treatment.

...

(m) *Home environment evaluation*. This is a single home visit to evaluate the potential impact of the home situation

on the rehabilitation goals.

[51 FR 41339, Nov. 14, 1986; 52 FR 4499, Feb. 12, 1987]

.....

§ 410.105 Requirements for coverage of CORF services.

Services specified in § 410.100 and not excluded under § 410.102 are covered as CORF services if they are furnished by a participating CORF (that is, a CORF that meets the conditions of subpart B of part 485 of this chapter, and has in effect a provider agreement under part 489 of this chapter) and if the following requirements are met:

(a) *Referral and medical history*. The services must be furnished to an individual who is referred by a physician who certifies that the individual needs skilled rehabilitation services, and makes the following information available to the CORF before or at the time treatment is begun:

- (1) The individual's significant medical history.
- (2) Current medical findings.
- (3) Diagnosis(es) and contraindications to any treatment modality.
- (4) Rehabilitation goals, if determined.

(b) *When and where services are furnished*.

- (1) All services must be furnished while the individual is under the care of a physician.
- (2) Except as provided in paragraph (b)(3) of this section, the services must be furnished on the premises of the CORF.

(3) *Exceptions*. (i) Physical therapy, occupational therapy, and speech pathology services may be furnished away from the premises of the CORF.

(ii) The single home visit specified in § 410.100(m) is also covered.

(c) *Plan of treatment.* (1) The services must be furnished under a written plan of treatment that—

- (i) Is established and signed by a physician before treatment is begun; and
- (ii) Prescribes the type, amount, frequency, and duration of the services to be furnished, and indicates the diagnosis and anticipated rehabilitation goals.

(2) The plan must be reviewed at least every 60 days by a facility physician who, when appropriate, consults with the professional personnel providing the services.

(3) The reviewing physician must certify or recertify that the plan is being followed, the patient is making progress in attaining the rehabilitation goals, and the treatment is having no harmful effects on the patient.

[51 FR 41339, Nov. 14, 1986, as amended at 56 FR 8841, Mar. 1, 1991]

§ 410.155 Outpatient mental health treatment limitation.

(a) *Limitation.* Only 62½ percent of the expenses incurred for services subject to the limit as specified in paragraph (b) of this section are considered incurred expenses under Medicare Part B when determining the amount of payment and deductible under §§ 410.152 and 410.160, respectively.

(b) *Application of the limitation—*(1) *Services subject to the limitation.* Except as specified in paragraph (b)(2) of this section, the following services are subject to the limitation if they are furnished in connection with the treatment of a mental, psychoneurotic, or personality disorder (that is, any condition identified by a diagnosis code within the range of 290 through 319) and are furnished to an individual who is not an inpatient of a hospital:

(i) **Services furnished by physicians and other practitioners, whether furnished directly or as an incident to those practitioners' services.**

(ii) Services provided by a CORF.

(2) *Services not subject to the limitation.* Services not subject to the limitation include the following:

- (i) Services furnished to a hospital inpatient.
- (ii) Brief office visits for the sole purpose of monitoring or changing drug prescriptions used in the treatment of mental, psychoneurotic, or personality disorders.
- (iii) Partial hospitalization services not directly provided by a physician.
- (iv) Diagnostic services, such as psychological testing, that are performed to establish a diagnosis.
- (v) Medical management, as opposed to psychotherapy, furnished to a patient diagnosed with Alzheimer's disease or a related disorder.

(c) *Examples.* (1) A clinical psychologist submitted a claim for \$200 for outpatient treatment of a beneficiary's mental disorder. The Medicare approved amount was \$180. Since clinical psychologists must accept assignment, the beneficiary is not liable for the \$20 in excess charges. The beneficiary previously satisfied the \$100 annual Part B deductible. The limitation reduces the amount of incurred expenses to 62½ percent of the approved amount. After subtracting any unmet deductible, Medicare pays 80 percent of the remaining incurred expenses. Medicare payment and beneficiary liability are computed as follows:

1. Actual charges	\$200.00
2. Medicare approved amount	180.00
3. Medicare incurred expenses (0.625×line 2).	112.50
4. Unmet deductible	0.00
5. Remainder after subtracting deductible (line 3 minus line 4)	112.50
6. Medicare payment (0.80 · line 5)	90.00
7. Beneficiary liability (line 2 minus line 6)	90.00

(2) A **clinical social worker** submitted a claim for \$135 for outpatient treatment of a beneficiary's mental disorder. The Medicare approved amount was \$120. Since clinical social workers must accept assignment, the beneficiary is not liable for the \$15 in excess

charges. The beneficiary previously satisfied \$70 of the \$100 annual Part B deductible, leaving \$30 unmet.

1. Actual charges	\$135.00
2. Medicare approved amount	120.00
3. Medicare incurred expenses (0.625 · line 2)	75.00
4. Unmet deductible	30.00
5. Remainder after subtracting deductible (line 3 minus line 4)	45.00
6. Medicare payment (0.80 · line 5)	36.00
7. Beneficiary liability (line 2 minus line 6)	84.00

(3) A physician who did not accept assignment submitted a claim for \$780 for services in connection with the treatment of a mental disorder that did not require inpatient hospitalization. The Medicare approved amount was \$750. Because the physician did not accept assignment, the beneficiary is liable for the \$30 in excess charges. The beneficiary had not satisfied any of the \$100 Part B annual deductible.

1. Actual charges	\$780.00
2. Medicare approved amount	750.00
3. Medicare incurred expenses (0.625 · line 2)	468.75
4. Unmet deductible	100.00
5. Remainder after subtracting deductible (line 3 minus line 4)	368.75
6. Medicare payment (0.80 · line 5)	95.00
7. Beneficiary liability (line 1 minus line 6)	485.00

(4) A beneficiary's only Part B expenses during 1995 were for a physician's services

in connection with the treatment of a mental disorder that initially required inpatient hospitalization. The remaining services were furnished on an outpatient basis. The beneficiary had not satisfied any of the \$100 annual Part B deductible in 1995. The physician, who accepted assignment, submitted a claim for \$780. The Medicare-approved amount was \$750. The beneficiary incurred \$350 of the approved amount while a hospital inpatient and incurred the remaining \$400 of the approved amount for outpatient services. Only \$400 of the approved amount is subject to the 621.2 percent limitation because the statutory limitation does not apply to services furnished to hospital inpatients.

1. Actual charges	\$780.00
2. Medicare approved amount	\$750.00
2A. Inpatient portion	\$350
2B. Outpatient portion	\$400
3. Medicare incurred expenses	\$600.00
3A. Inpatient portion	\$350
3B. Outpatient portion (0.625 · line 2B) ..	\$250
4. Unmet deductible	\$100.00
5. Remainder after subtracting deductible (line 3 minus line 4)	\$500.00
6. Medicare payment (0.80 · line 5)	\$400.00
7. Beneficiary liability (line 2 minus line 6)	\$350.00

[63 FR 20129, Apr. 23, 1998]

PART 485--CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

Subpart B—Conditions of Participation: Comprehensive Outpatient Rehabilitation Facilities

§ 485.50 Basis and scope.

This subpart sets forth the conditions that facilities must meet to be certified as comprehensive outpatient rehabilitation facilities (CORFs) under section 1861(cc)(2) of the Social Security Act and be accepted for participation in Medicare in accordance with part 489 of this chapter.

§ 485.58 Condition of participation: Comprehensive rehabilitation program.

The facility must provide a coordinated rehabilitation program that includes, at a minimum, physicians' services, physical therapy services, and **social or psychological services**. The services must be furnished by personnel that meet the qualifications set forth in § 485.70 and must be consistent with the plan of treatment and the results of comprehensive patient assessments.

(a) *Standard: Physician services.* (1) A facility physician must be present in the facility for a sufficient time to—

- (i) Provide, in accordance with accepted principles of medical practice, medical direction, medical care services, and consultation;
- (ii) Establish the plan of treatment in cases where a plan has not been established by the referring physician;
- (iii) Assist in establishing and implementing the facility's patient care policies; and
- (iv) Participate in plan of treatment reviews, patient case review conferences, comprehensive patient assessment and reassessments, and utilization review.

(2) The facility must provide for emergency physician services during the facility operating hours.

(b) *Standard: Plan of treatment.* For each patient, a physician must establish a plan of treatment before the facility initiates treatment. The plan of treatment must meet the following requirements:

- (1) It must delineate anticipated goals and specify the type, amount, frequency and duration of services to be provided.
- (2) It must be promptly evaluated after changes in the patient's condition and revised when necessary.
- (3) It must, if appropriate, be developed in consultation with the facility physician and the appropriate facility professional personnel.
- (4) It must be reviewed at least every 60 days by a facility physician who, when appropriate, consults with the professional personnel providing services. The results of this review must be communicated to the patient's referring physician for concurrence before treatment is continued or discontinued.
- (5) It must be revised if the comprehensive reassessment of the patient's status or the results of the patient case review conference indicate the need for revision.

(c) *Standard: Coordination of services.* The facility must designate, in writing, a qualified professional to ensure that professional personnel coordinate their related activities and exchange information about each patient under their care. Mechanisms to assist in the coordination of services must include—

- (1) Providing to all personnel associated with the facility, a schedule indicating the frequency and type of services provided at the facility;

(2) A procedure for communicating to all patient care personnel pertinent information concerning significant changes in the patient's status;

(3) Periodic clinical record entries, noting at least the patient's status in relationship to goal attainment; and

(4) Scheduling patient case review conferences for purposes of determining appropriateness of treatment, when indicated by the results of the initial comprehensive patient assessment, reassessment(s), the recommendation of the facility physician (or other physician who established the plan of treatment), or upon the recommendation of one of the professionals providing services.

(d) *Standard: Provision of services.* (1) All patients must be referred to the facility by a physician who provides the following information to the facility before treatment is initiated:

- (i) The patient's significant medical history.
- (ii) Current medical findings.
- (iii) Diagnosis(es) and contraindications to any treatment modality.
- (iv) Rehabilitation goals, if determined.

(2) Services may be provided by facility employees or by others under arrangements made by the facility.

(3) The facility must have on its premises the necessary equipment to implement the plan of treatment and sufficient space to allow adequate care.

(4) The services must be furnished by personnel that meet the qualifications of § 485.70 and the number of qualified personnel must be adequate for the volume and diversity of services offered.

Personnel that do not meet the qualifications specified in § 485.70 may be used by the facility in assisting qualified staff. When a qualified individual is assisted by these personnel, the qualified individual must be on the premises, and must instruct these personnel in appropriate patient care service

techniques and retain responsibility for their activities.

(5) A qualified professional must initiate and coordinate the appropriate portions of the plan of treatment, monitor the patient's progress, and recommend changes, in the plan, if necessary.

(6) A qualified professional representing each service made available at the facility must be either on the premises of the facility or must be available through direct telecommunication for consultation and assistance during the facility's operating hours. At least one qualified professional must be on the premises during the facility's operating hours.

(7) All services must be provided consistent with accepted professional standards and practice.

(e) *Standard: Scope and site of services* —(1) *Basic requirements.* The facility must provide all the CORF services required in the plan of treatment and, except as provided in paragraph (e)(2) of this section, must provide the services on its premises.

(2) *Exceptions.* Physical therapy, occupational therapy, and speech pathology services furnished away from the premises of the CORF may be covered as CORF services if Medicare payment is not otherwise made for these services. In addition, a single **home visit** is covered if there is need to evaluate the potential impact of the home environment on the rehabilitation goals.

(f) *Standard: Patient assessment.* **Each qualified professional involved in the patient's care**, as specified in the plan of treatment, must—

- (1) Carry out an initial patient assessment; and
- (2) In order to identify whether or not the current plan of treatment is appropriate, perform a patient reassessment after significant changes in the patient's status.

(g) *Standard: Laboratory services.* (1) If the facility provides its own laboratory services, the services must meet the applicable requirements for laboratories specified in part 493 of this chapter.

(2) If the facility chooses to refer specimens for laboratory testing, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the requirements of part 493 of this chapter.

[48 FR 56293, Dec. 15, 1982, as amended at 56 FR 8852, Mar. 1, 1991; 57 FR 7137, Feb. 28, 1992]

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§ 485.70 Personnel qualifications.

This section sets forth the qualifications that must be met, as a condition of participation, under § 485.58, and as a condition of coverage of services under § 410.100 of this chapter.

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(1) A ***social worker*** must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Hold at least a bachelor's degree from a school accredited or approved by the

Council on Social Work Education; and

(3) Have 1 year of social work experience in a health care setting.

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[48 FR 56293, Dec. 15, 1982. Redesignated and amended at 50 FR 33034, Aug. 16, 1985; 51 FR 41352, Nov. 14, 1986; 60 FR 2327, Jan. 9, 1995]

Medicare Benefit Policy Manual
CHAPTER 12 - COMPREHENSIVE OUTPATIENT REHABILITATION FACILITY
(CORF) COVERAGE

20 - Required and Optional CORF Services

(Rev. 1, 10-01-03)

A3-3180, CORF-250

20.1 - Required Services

(Rev. 21, Issued: 09-24-04, Effective: 06-30-04, Implementation: 10-25-04)

*A CORF is defined as a facility that is primarily engaged in providing diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of the injured and disabled or to patients recovering from illness. The CORF must provide a comprehensive, coordinated, skilled rehabilitation program for its patients that includes, at a minimum, CORF physicians' services, physical therapy services, and **social or psychological services**. A physician must certify, as a condition of payment, that CORF services are required because the individual needs skilled rehabilitation services. Skilled rehabilitation services are defined as services requiring the skills of physical therapists, speech-language pathologists, or occupational therapists. In the CORF setting respiratory therapy services can be provided by physical therapists, occupational therapists, respiratory therapists or registered nurses, as recognized by applicable State law.*

A CORF is recognized as a provider of services that is paid under the physician fee schedule for all services except for drugs and biologicals. To participate as a CORF, a facility or provider must furnish, as its major services, at least the following to patients requiring skilled rehabilitation services:

- CORF physicians' services (rendered by a physician) - professional services performed by physicians, such as consultation, home, office, and institutional evaluation and management services rendered by a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he/she performs services (42 CFR 410.100(a)). The physician must have had, subsequent to completing a 1-year hospital internship, at least one year of training in the medical management of patients requiring rehabilitative services; (§485.70) or has had at least 1 year of full-time or part-time experience in a rehabilitation setting providing physician's services similar to those required in a rehabilitation facility. A physician who is specialized only in pulmonary rehabilitation are not likely to have the experience needed to medically manage patients that need skilled rehabilitation services;*
- Physical therapy - services include testing, measurement, assessment and treatment of the function, or dysfunction, of the neuromuscular, musculoskeletal, cardiovascular and respiratory system, and establishment of a maintenance therapy program for an individual whose restoration potential has been reached (42 CFR 410.100(b)); and*

- **Social or psychological services** – *social services include assessment of the social and emotional factors related to the individual's illness, need for care, response to treatment, adjustment to care furnished, casework services to assist in resolving social or emotional problems that may have an adverse effect on the beneficiary's ability to respond to treatment and assessment of the relationship of the individual's medical and nursing requirements to his or her home situation, financial resources, and the community resources available upon discharge from the CORF (42 CFR 410.100(h)). Psychological services include assessment, diagnosis and treatment of an individual's mental and emotional functioning as it relates to the individual's rehabilitation, psychological evaluations of the individual's progress under the treatment plan, and assessment of those aspects of an individual's family and home situation that affects the individual's rehabilitation treatment (42 CFR 410.100(i));*

In addition to this basic package of *medically necessary comprehensive coordinated skilled rehabilitation* services, the CORF may furnish as many of the other *covered* items and services listed in §20.2 as it *elects, as long as they are consistent with the plan of treatment, necessary to achieve the rehabilitation goals and performed in conjunction with core CORF services.*

To receive Medicare payment for covered services, the CORF must have adequate space and equipment necessary for any of the services provided. *Additionally, in order to accept a patient, the CORF must be able to provide all of the services required by the patient, as established in the plan of treatment. If the CORF does not have personnel to provide the service, it must arrange for the services to be provided at the CORF, as needed, by outside practitioners. In general, all services must be furnished on the premises of the CORF. The only exceptions are the home evaluation, physical therapy, occupational therapy, and speech-language pathology services. There is no restriction on where these services may be furnished with the exception of home evaluations. The home evaluation may be covered if furnished pursuant to the plan of treatment, and it does not duplicate services for which payment has been made under Medicare. The CORF must bill their assigned fiscal intermediary, which makes payment for services provided under this arrangement.*

The CORF services are subject to the Medicare Part B deductible and coinsurance provisions, *i.e., the CORF may bill the beneficiary only for the unmet portion of the deductible and 20 percent of the fee schedule amount for covered services, unless the services are subject to the outpatient mental health treatment limitation for psychological therapy.*

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40.7 - Social Services

(Rev. 21, Issued: 09-24-04, Effective: 06-30-04, Implementation: 10-25-04)

A3-3183.7, CORF-253.7

Social services *are covered CORF services if they are part of a comprehensive coordinated skilled rehabilitation program, included in the plan of treatment established and signed by the*

referring physician, and performed in conjunction with core CORF services. Social services must contribute to the improvement of the individual's condition. Such services include:

- Assessment of the social and emotional factors related to the patient's illness, need for care, response to treatment, and adjustment to care in the CORF;
- Assessment of the relationship of the patient's medical and nursing requirements to his or her home situation, financial resources, and the community resources available upon discharge from the CORF; and
- Counseling and referral for casework assistance in resolving problems in these areas.

REHABILITATION AGENCY — SOCIAL SERVICES/SOCIAL WORKER

According to the regulations, a rehabilitation agency is defined as a public or private agency that provides on an outpatient basis an integrated multidisciplinary program designed to upgrade the physical function of handicapped and disabled individuals through a team of specialized rehabilitation personnel. This type of agency is required to provide physical therapy or speech pathology services, and social or vocational adjustment services. A rehabilitation agency differs from a comprehensive outpatient rehabilitation facility (CORF) discussed in the previous section, in that a CORF is mandated by statute to include a broader range of rehabilitation services that includes social and psychological services. The rehabilitation agency is, on the other hand, much more narrow in focus; although they are required to provide social or vocational adjustment services, such services are not reimbursable under Medicare.

In a rehabilitation agency, the regulations require that a qualified social worker or psychologist render the social and vocational adjustment services. (In agencies in which only vocational counseling is involved, a qualified vocational specialist can provide such services.) The agency can choose to provide such services through staff positions or through some other arrangement.

Social and vocational adjustment services are not provided routinely. Rather, an evaluation is made of the social and vocational factors involved in a patient's rehabilitation. If it is determined that such services are needed, then the agency must make an appropriate arrangement. Because Medicare does not reimburse for social and vocational adjustment services, the reality is that rehabilitation agencies do not generally encourage use of such services. Furthermore, if a patient is in need of social or vocational adjustment services and is a patient at another facility that does provide these services, such as a nursing home, the rehabilitation agency is not required to provide these services. In this case, there must be a written agreement or contract between the rehabilitation agency and the other provider specifying that the other provider or facility is responsible for the social or vocational adjustment services.

As with most Part B Medicare benefits, the regulations require that social and vocational adjustment services can be made only with a physician's order, which establishes the goals for treatment. A written plan of care must be developed for each patient by a physician or a qualified physical therapist and must be periodically reviewed by a physician.

As defined in the regulations, a social worker must be licensed by the state if applicable, be a graduate of a school of social work accredited or approved by the Council on Social Work Education, and have one year of social work experience in a health care setting.

SOCIAL SECURITY ACT § 1861

42USC1395x

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part D--Miscellaneous Provisions

Sec. 1395x. Definitions

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(p) Outpatient physical therapy services

The term "outpatient physical therapy services" means physical therapy services furnished by a provider of services, a clinic, rehabilitation agency, or a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient--

(1) who is under the care of a physician (as defined in paragraph (1), (3), or (4) of subsection (r) of this section), and

(2) with respect to whom a plan prescribing the type, amount, and duration of physical therapy services that are to be furnished such individual has been established by a physician (as so defined) or by a qualified physical therapist and is periodically reviewed by a physician (as so defined);

excluding, however--

(3) any item or service if it would not be included under subsection (b) of this section if furnished to an inpatient of a hospital; and

(4) any such service--

(A) if furnished by a clinic or rehabilitation agency, or by others under arrangements with such clinic or agency, unless such clinic or rehabilitation agency--

(i) provides an adequate program of physical therapy services for outpatients and has the facilities and personnel required for such program or required for the supervision of such a program, in accordance with such requirements as the Secretary may specify,

(ii) has policies, established by a group of professional personnel, including one or more physicians (associated with the clinic or rehabilitation agency) and one or more qualified physical therapists, to govern the services (referred to in clause (i)) it provides,

(iii) maintains clinical records on all patients,

(iv) if such clinic or agency is situated in a State in which State or applicable local law provides for the licensing of institutions of this nature, (I) is licensed pursuant to such law, or (II) is approved by the agency of such State or locality responsible for licensing institutions of this nature, as meeting the standards established for such licensing; and

(v) meets such other conditions relating to the health and safety of individuals who are furnished services by such clinic or agency on an outpatient basis, as the Secretary may find necessary, and provides the Secretary on a continuing basis with a surety bond in a form specified by the Secretary and in an amount that is not less than \$50,000, or

(B) if furnished by a public health agency, unless such agency meets such other conditions relating to health and safety of individuals who are furnished services by such agency on an outpatient basis, as the Secretary may find necessary.

The term "outpatient physical therapy services" also includes physical therapy services furnished an individual by a physical therapist (in his office or in such individual's home) who meets licensing and other standards prescribed by the Secretary in regulations, otherwise than under an arrangement with and under the supervision of a provider of services, clinic, rehabilitation agency, or public health

agency, if the furnishing of such services meets such conditions relating to health and safety as the Secretary may find necessary. In addition, such term includes physical therapy services which meet the requirements of the first sentence of this subsection except that they are furnished to an individual as an inpatient of a hospital or extended care facility. The term "outpatient physical therapy services" also includes speech-language pathology services furnished by a provider of services, a clinic, rehabilitation agency, or by a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient, subject to the conditions prescribed in this subsection. Nothing in this subsection shall be construed as requiring, with respect to outpatients who are not entitled to benefits under this subchapter, a physical therapist to provide outpatient physical therapy services only to outpatients who are under the care of a physician or pursuant to a plan of care established by a physician. The Secretary may waive the requirement of a surety bond under paragraph (4)(A)(v) in the case of a clinic or agency that provides a comparable surety bond under State law.

PART 485--CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

Subpart H—Conditions of Participation for Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services

§ 485.701 Basis and scope.

This subpart implements section 1861(p)(4) of the Act, which—

- (a) Defines outpatient physical therapy and speech pathology services;
- (b) Imposes requirements with respect to adequate program, facilities, policies, staffing, and clinical records; and
- (c) Authorizes the Secretary to establish by regulation other health and safety requirements.

[60 FR 2327, Jan. 9, 1995]

§ 485.703 Definitions.

Clinic. A facility that is established primarily to furnish outpatient physician services and that meets the following tests of physician involvement:

- (1) The medical services are furnished by a group of three or more physicians practicing medicine together.
- (2) A physician is present during all hours of operation of the clinic to furnish medical services, as distinguished from purely administrative services.

Organization. A clinic, rehabilitation agency, or public health agency.

Public health agency. An official agency established by a State or local government, the primary function of which is to maintain the health of the population served by performing environmental health services, preventive medical services, and in certain cases, therapeutic services.

Rehabilitation agency. An agency that—

- (1) Provides an integrated interdisciplinary rehabilitation program designed to upgrade the physical functioning of handicapped disabled individuals by bringing specialized rehabilitation staff together to perform as a team; and
- (2) Provides at least the following services:
 - (i) Physical therapy or speech-language pathology services.

- (ii) **Social or vocational adjustment services.**

Supervision. Authoritative procedural guidance that is for the accomplishment of a function or activity and that—

- (1) Includes initial direction and periodic observation of the actual performance of the function or activity; and

- (2) Is furnished by a qualified person —

- (i) Whose sphere of competence encompasses the particular function or activity; and
 - (ii) Who (unless otherwise provided in this subpart) is on the premises if the person performing the function or activity does not meet the assistant-level practitioner qualifications specified in § 485.705.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988; 54 FR 38679, Sept. 20, 1989. Redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

§ 485.705 Personnel qualifications.

(a) *General qualification requirements.*

Except as specified in paragraphs (b) and (c) of this section, all personnel who are involved in the furnishing of outpatient physical therapy, occupational therapy, and speech-language pathology services directly by or under arrangements with an organization must be legally authorized (licensed or, if applicable, certified or registered) to practice by the State in which they perform the functions or actions, and must act only within the scope of their State license or State certification or registration.

(b) *Exception for Federally defined qualifications.* The following Federally defined qualifications must be met:

- (1) For a physician, the qualifications and conditions as defined in section 1861(r) of the Act and the requirements in part 484 of this chapter.

- (2) *For a speech-language pathologist*, the qualifications specified in section 1861(11)(1) of the Act and the requirements in part 484 of this chapter.

(c) *Exceptions when no State Licensing laws or State certification or registration requirements exist.* If no State licensing laws or State certification or registration requirements exist for the profession, the following requirements must be met—

- (1) An *administrator* is a person who has a bachelor's degree and:

- (i) Has experience or specialized training in the administration of health institutions or agencies; or
 - (ii) Is qualified and has experience in one of the professional health disciplines.

- (2) An *occupational therapist* must meet the requirements in part 484 of this chapter.

- (3) An *occupational therapy assistant* must meet the requirements in part 484 of this chapter.

- (4) A *physical therapist* must meet the requirements in part 484 of this chapter.

- (5) A *physical therapist assistant* must meet the requirements in part 484 of this chapter.
- (6) A **social worker** must meet the requirements in part 484 of this chapter.
- (7) A *vocational specialist* is a person who has a baccalaureate degree and—
- (i) Two years experience in vocational counseling in a rehabilitation setting such as a sheltered workshop, State employment service agency, etc.; or
 - (ii) At least 18 semester hours in vocational rehabilitation, educational or vocational guidance, psychology, **social work**, special education or personnel administration, and 1 year of experience in vocational counseling in a rehabilitation setting; or
 - (iii) A master's degree in vocational counseling.
- (8) A nurse practitioner is a person who must:
- (i) Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law; *and*
 - (ii) Be certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners; *or*
 - (iii) Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law and have been granted a Medicare billing number as a nurse practitioner by December 31, 2000; *or*
 - (iv) Be a nurse practitioner who on or after January 1, 2001, applies for a Medicare billing number for the first time and meets the standards for nurse practitioners in paragraphs (c)(8)(i) and (c)(8)(ii) of this section; *or*
 - (v) Be a nurse practitioner who on or after January 1, 2003, applies for a Medicare billing number for the first time and possesses a master's degree in nursing and meets the standards for nurse practitioners in paragraphs (b)(1)(i) and (b)(1)(ii) of this section.
- (9) A *clinical nurse specialist* is a person who must:
- (i) Be a registered nurse who is currently licensed to practice in the State where he or she practices and be authorized to perform the services of a clinical nurse specialist in accordance with State law;
 - (ii) Have a master's degree in a defined clinical area of nursing from an accredited educational institution; and,
 - (iii) Be certified as a clinical nurse specialist by the American Nurses Credentialing Center.
- (10) A *physician assistant* is a person who:
- (i) Has graduated from a physician assistant educational program that is accredited by the Commission on Accreditation of Allied Health Education Programs; or
 - (ii) Has passed the national certification examination that is administered by the National Commission on Certification of Physician Assistants; and
 - (iii) Is licensed by the State to practice as a physician assistant.
- [63 FR 58912, Nov. 2, 1998; 64 FR 25457, May 12, 1999; 64 FR 59442, Nov. 2, 1999]

§ 485.707 Condition of participation: Compliance with Federal, State, and local laws.

The organization and its staff are in compliance with all applicable Federal, State, and local laws and regulations.

(a) *Standard: Licensure of organization.*

In any State in which State or applicable local law provides for the licensing of organizations, a clinic, rehabilitation agency, or public health agency is licensed in accordance with applicable laws.

(b) *Standard: Licensure or registration of personnel.*

Staff of the organization are licensed or registered in accordance with applicable laws.

[41 FR 20865, May 21, 1976, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995]

§ 485.709 Condition of participation: Administrative management.

The clinic or rehabilitation agency has an effective governing body that is legally responsible for the conduct of the clinic or rehabilitation agency. The governing body designates an administrator, and establishes administrative policies.

(a) *Standard: Governing body.* There is a governing body (or designated person(s) so functioning) which assumes full legal responsibility for the overall conduct of the clinic or rehabilitation agency and for compliance with applicable laws and regulations. The name of the owner(s) of the clinic or rehabilitation agency is fully disclosed to the State agency. In the case of corporations, the names of the corporate officers are made known.

(b) *Standard: Administrator.* The governing body—

- (1) Appoints a qualified full-time administrator;
- (2) Delegates to the administrator the internal operation of the clinic or rehabilitation agency in accordance with written policies;
- (3) Defines clearly the administrator's responsibilities for procurement and direction of personnel; and
- (4) Designates a competent individual to act during temporary absence of the administrator.

(c) *Standard: Personnel policies.* Personnel practices are supported by appropriate written personnel policies that are kept current. Personnel records include the qualifications of all professional and assistant level personnel, as well as evidence of State licensure if applicable.

(d) *Standard: Patient care policies.* Patient care practices and procedures are supported by written policies established by a group of professional personnel including one or more physicians associated with the clinic or rehabilitation agency, one or more qualified physical therapists (if physical therapy services are provided), and one or more qualified speech pathologists (if speech pathology services are provided). The policies govern the outpatient physical

therapy and/or speech pathology services and related services that are provided. These policies are evaluated at least annually by the group of professional personnel, and revised as necessary based upon this evaluation.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988. Redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

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**§ 485.717 Condition of participation:
Rehabilitation program.**

This condition and its standards apply only to a rehabilitation agency's own patients, not to patients of hospitals, skilled nursing facilities (SNFs), or Medicaid nursing facilities (NFs) to whom the agency furnishes services. (The hospital, SNF, or NF is responsible for ensuring that qualified staff furnish services for which they arrange or contract for their patients.) The rehabilitation agency provides, in addition to physical therapy and speech- language pathology services, **social or vocational adjustment services** to all of its patients who need them. The agency provides for special qualified staff to evaluate the social and vocational factors, to counsel and advise on the social or vocational problems that arise from the patient's illness or injury, and to make appropriate referrals for needed services.

(a) Standard: Qualification of staff.

The agency's social or vocational adjustment services are furnished as appropriate, by qualified psychologists, **qualified social workers**, or qualified vocational specialists. Social or vocational adjustment services may be performed by a qualified psychologist or **qualified social worker**. Vocational adjustment services may be furnished by a qualified vocational specialist.

(b) Standard: Arrangements for social or vocational adjustment services. (1) If a rehabilitation agency does not provide social or vocational adjustment services through salaried employees, it may provide those services through a written contract with others who meet the requirements and responsibilities set forth in this subpart for salaried personnel.

(2) The contract must specify the term of the contract and the manner of termination or renewal and provide that the agency retains responsibility for the control and supervision of the services.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 56 FR 46562, Sept. 13, 1991. Redesignated and amended at 60 FR 2326, 2328, Jan. 9, 1995; 60 FR 11632, Mar. 2, 1995; 60 FR 50447, Sept. 29, 1995]

State Operations Manual
APPENDIX E - GUIDANCE TO SURVEYORS: OUTPATIENT PHYSICAL THERAPY OR
SPEECH PATHOLOGY SERVICES
(Rev. 1, 05-21-04)

§485.717 Condition for Coverage: Rehabilitation Program

Interpretive Guidelines §485.717

A rehabilitation agency must provide either physical therapy or speech pathology services plus a rehabilitation program which minimally includes **social or vocational adjustment services**. Such services may be furnished directly or under arrangement. Section 485.717 requires the rehabilitation agency to provide social or vocational adjustment services to all patients in need of such services. The agency's qualified staff (485.717(a) (psychologist, **social worker** or vocational specialist) must evaluate (through a face-to-face assessment) the social or vocational factors involved in a patient's rehabilitation program, counsel and advise on social or vocational problems due to the patient's injury or illness, and make appropriate referrals for required services. However, there are circumstances when the provision of these services to certain patients by the rehabilitation agency would be unnecessary or would duplicate similar services provided by other organizations. The rehabilitation agency is neither required to evaluate patients nor to provide social or vocational adjustment services to patients under any of the following situations:

- The patient's file is clearly documented to indicate that the patient does not require social vocational adjustment services. The documentation must be provided by a physician, qualified psychologist, **social worker**, or vocational specialist.
- The patient is receiving social or vocational adjustment services as an inpatient or outpatient of another provider or supplier of services, and a written agreement or contract between the rehabilitation agency and the provider or supplier specifies that the provider or supplier is responsible for social or vocational adjustment services for all patients receiving OPT/OSP from the rehabilitation agency.
- The other provider or supplier agrees in the written contract with the rehabilitation agency to clearly mark or identify the files of patients receiving OPT/OSP who have previously been evaluated for social or vocational adjustment services. A separate evaluation by the rehabilitation agency of those patients for social or vocational adjustment services is not required.
- The OPT/OSP provider provides diagnostic or therapeutic services to individuals for whom another agency or organization has overall responsibility. For example, if a speech pathology evaluation and therapy services are provided to students under a contract with a school system, the OSP provider is neither required to evaluate the need for, nor provide, speech pathology services since the school system is responsible for meeting the overall needs of students within its jurisdiction.

When a rehabilitation agency accepts a patient whose social or vocational status is not covered by one of the above situations, the agency's qualified staff must determine whether the patient's physical illness or injury indicates the need for social or vocational adjustment services. The patient's clinical record should indicate that this determination is based on information collected and reviewed by the qualified staff. Social or vocational adjustment services may be provided either on the premises or off the premises of the organization (e.g., in the office of the psychologist).

Major Sources of Information

- Contract for services under arrangement;
- Personnel records - job descriptions, employee qualifications and health examinations as specified;

- Clinical records;
- Patient care policies.

§485.717(a) Standard: Qualifications of Staff

Interpretive Guidelines §485.717(a)

All personnel providing social or vocational adjustment services must meet the qualifications for psychologist, **social worker** (485.705(c)(6)), or vocational specialist (485.705(c)(7)), as appropriate).

§485.717(b) Standard: Arrangements for Social or Vocational Adjustment Services

Interpretive Guidelines §485.717(b)

If an agency does not provide social or vocational adjustment services through its own employees, such services may be provided by means of written agreements with individuals or organizations. Their contracts must retain the agency's responsibility, control and supervision over the services and must contain details prescribed in 485.717(b). These details are listed on the [CMS-1893](#). The appropriate professional staff of the organization (psychologists, **social workers**, vocational specialists) are responsible for developing, in conjunction with the physician, the regimen of social or vocational adjustment services to be provided to individuals requiring such services and must assume the professional and administrative responsibility for services provided under arrangements.

PARTIAL HOSPITALIZATION FOR THE TREATMENT OF MENTAL ILLNESS — SOCIAL WORK SERVICES

Section 4070 of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) amended the Social Security Act to provide for coverage under Medicare of partial hospitalization services related to the treatment of mental illness.

This provision, which became effective December 22, 1987, covers services that are provided by a hospital-based or hospital-affiliated program that is a distinct and organized intensive ambulatory treatment service offering less than 24-hour daily care. In OBRA '90, Section 4162, the law was amended further to provide for coverage of partial hospitalization services in community mental health centers (CMHCs) that meet certain applicable state licensing or certification requirements and the definition of CMHCs in the Public Health Service Act. The OBRA '90 amendment became effective October 1, 1991.

To be covered, the law states that the services must be reasonable and necessary for the diagnosis or active treatment of the patient's condition, and must reasonably be expected to improve or maintain the individual's condition and functional level to prevent relapse or hospitalization. Partial hospitalization services must be prescribed, supervised, and reviewed by a physician in accordance with an individualized plan of treatment. Appropriate staff participating in the treatment must be consulted.

Under this provision, Medicare covers individual and group therapy with physicians, psychologists, or other mental health professionals to the extent authorized under state law; occupational therapy; services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients; individualized activity therapies that are not primarily recreational; family counseling; patient training and education; and diagnostic services. (See the statutory citation and regulations for the complete list of covered items and services.) The law specifically identifies social workers and the regulations provide guidelines for clinical social worker qualifications. Clinical social workers must possess a master's or doctoral degree in social work, have performed at least two years of supervised clinical social work, and be certified or licensed as a clinical social worker.

Clinical social work services are reimbursed at a lower level than psychological services. The statute stipulates that amounts paid for clinical social worker services be "80 percent of the lesser of (i) the actual charge for the services or (ii) 75 percent of the amount determined for payment of a psychologist." (42ISC1395k)

For the most part, CMS regulations repeat what is in the statute with some further explanation of treatment plan requirements (42 CFR 424.24(e)). It is important to note that the statute provides for regulations that would establish guidelines related to the frequency and duration of services taking into account accepted norms of medical practice and the reasonable expectation of patient improvement. The regulations leave it to the individual physician to establish how often and for how long partial hospitalization services are needed.

SOCIAL SECURITY ACT § 1831

42USC1395j

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part B--Supplementary Medical Insurance Benefits for Aged and Disabled

Sec. 1395j. Establishment of supplementary medical insurance program for aged and disabled

There is hereby established a voluntary insurance program to provide medical insurance benefits in accordance with the provisions of this part for aged and disabled individuals who elect to enroll under such program, to be financed from premium payments by enrollees together with contributions from funds appropriated by the Federal Government.

(Aug. 14, 1935, ch. 531, title XVIII, Sec. 1831, as added Pub. L. 89-97, title I, Sec. 102(a), July 30, 1965, 79 Stat. 301; amended Pub. L. 92-603, title II, Sec. 201(a)(3), Oct. 30, 1972, 86 Stat. 1371.)

Amendments

1972--Pub. L. 92-603 substituted ``aged and disabled individuals" for ``individuals 65 years of age or over".

Study Regarding Coverage Under Part B of Medicare for Nonreimbursable Services Provided by Optometrists for Prosthetic Lenses for Patients With Aphakia

Pub. L. 94-182, title I, Sec. 109, Dec. 31, 1975, 89 Stat. 1053, provided that the Secretary of Health, Education, and Welfare conduct a study on the appropriateness of reimbursement under the insurance program established by this part for services performed by optometrists with respect to the provision of prosthetic lenses for patients with aphakia and submit such study to Congress not later than 4 months after Dec. 31, 1975.

Study To Determine Feasibility of Inclusion of Certain Additional Services Under Part B

Pub. L. 90-248, title I, Sec. 141, Jan. 2, 1968, 81 Stat. 855, directed Secretary to conduct a study relating to inclusion under the supplementary medical insurance program under this part of services of additional types of licensed practitioners performing health services in independent practice and submit such study to Congress prior to Jan. 1, 1969.

SOCIAL SECURITY ACT § 1832

Section Referred to in Other Sections

This section is referred to in title 38 sections 1725, 1729.

42USC1395k

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part B--Supplementary Medical Insurance Benefits for Aged and Disabled

Sec. 1395k. Scope of benefits; extension of coverage of immunosuppressive drugs; definitions
(a) Scope of benefits

The benefits provided to an individual by the insurance program established by this part shall consist of--

(1) entitlement to have payment made to him or on his behalf (subject to the provisions of this part) for medical and other health services, except those described in subparagraphs (B) and (D) of paragraph (2) and subparagraphs (E) and (F) of section 1395u(b)(6) of this title; and

(2) entitlement to have payment made on his behalf (subject to the provisions of this part) for--
.....

(J) partial hospitalization services provided by a community mental health center (as described in section 1395x(ff)(2)(B) of this title).
.....

SOCIAL SECURITY ACT § 1833

42USC1395I

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part B--Supplementary Medical Insurance Benefits for Aged and Disabled

Sec. 1395I. Payment of benefits

(a) Amounts

Except as provided in section 1395mm of this title, and subject to the succeeding provisions of this section, there shall be paid from the Federal Supplementary Medical Insurance Trust Fund, in the case of each individual who is covered under the insurance program established by this part and incurs expenses for services with respect to which benefits are payable under this part, amounts equal to--

(1) in the case of services described in section 1395k(a)(1) of this title--80 percent of the reasonable charges for the services; except that (A) an organization which provides medical and other health services (or arranges for their availability) on a prepayment basis (and either is sponsored by a union or employer, or does not provide, or arrange for the provision of, any inpatient hospital services) may elect to be paid 80 percent of the reasonable cost of services for which payment may be made under this part on behalf of individuals enrolled in such organization in lieu of 80 percent of the reasonable charges for such services if the organization undertakes to charge such individuals no more than 20 percent of such reasonable cost plus any amounts payable by them as a result of subsection (b) of this section, (B) with respect to items and services described in section 1395x(s)(10)(A) of this title, the amounts paid shall be 100 percent of the reasonable charges for such items and services, (C) with respect to expenses incurred for those physicians' services for which payment may be made under this part that are described in section 1395y(a)(4) of this title, the amounts paid shall be subject to such limitations as may be prescribed by regulations, (D) with respect to clinical diagnostic laboratory tests for which payment is made under this part (i) on the basis of a fee schedule under subsection (h)(1) of this section or section 1395m(d)(1) of this title, the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis or which are furnished on an outpatient basis by a critical access hospital) of the lesser of the amount determined under such fee schedule, the limitation amount for that test determined under subsection (h)(4)(B) of this section, or the amount of the charges billed for the tests, or (ii) on the basis of a negotiated rate established under subsection (h)(6) of this section, the amount paid shall be equal to 100 percent of such negotiated rate, (E) with respect to services furnished to individuals who have been determined to have end stage renal disease, the amounts paid shall be determined subject to the provisions of section 1395rr of this title, (F) with respect to **clinical social worker services** under

section 1395x(s)(2)(N) of this title, the amounts paid shall be 80 percent of the lesser of (i) the actual charge for the services or (ii) 75 percent of the amount determined for payment of a psychologist under clause (L), [(G) Repealed. Pub. L. 103-432, title I, Sec. 156(a)(2)(B)(ii), Oct. 31, 1994, 108 Stat. 4440,]

.....

(c) Mental disorders

Notwithstanding any other provision of this part, with respect to expenses incurred in any calendar year in connection with the treatment of mental, psychoneurotic, and personality disorders of an individual who is not an inpatient of a hospital at the time such expenses are incurred, there shall be considered as incurred expenses for purposes of subsections (a) and (b) of this section only 62½ percent of such expenses. For purposes of this subsection, the term "treatment" does not include brief office visits (as defined by the Secretary) for the sole purpose of monitoring or changing drug prescriptions used in the treatment of such disorders or partial hospitalization services that are not directly provided by a physician.

SOCIAL SECURITY ACT § 1835

42USC1395n

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part B--Supplementary Medical Insurance Benefits for Aged and Disabled

Sec. 1395n. Procedure for payment of claims of providers of services

(a) Conditions for payment for services described in section 1395k(a)(2) of this title

Except as provided in subsections (b), (c), and (e) of this section, payment for services described in section 1395k(a)(2) of this title furnished an individual may be made only to providers of services which are eligible therefor under section 1395cc(a) of this title, and only if--

(1) written request, signed by such individual, except in cases in which the Secretary finds it impracticable for the individual to do so, is filed for such payment in such form, in such manner and by such person or persons as the Secretary may by regulation prescribe, no later than the close of the period of 3 calendar years following the year in which such services are furnished (deeming any services furnished in the last 3 calendar months of any calendar year to have been furnished in the succeeding calendar year) except that, where the Secretary deems that efficient administration so requires, such period may be reduced to not less than 1 calendar year; and

(2) a physician certifies (and recertifies, where such services are furnished over a period of time, in such cases, with such frequency, and accompanied by such supporting material, appropriate to the case involved, as may be provided by regulations) that--

(A) in the case of home health services (i) such services are or were required because the individual is or was confined to his home (except when receiving items and services referred to in section 1395x(m)(7) of this title) and needs or needed skilled nursing care (other than solely venipuncture for the purpose of obtaining a blood sample) on an intermittent basis or physical or speech therapy or, in the case of an individual who has been furnished home health services based on such a need and who no longer has such a need for such care or therapy, continues or continued to need occupational therapy, (ii) a plan for furnishing such services to such individual has been established and is periodically reviewed by a physician, and (iii) such services are or were furnished while the individual is or was under the care of a physician;

(B) in the case of medical and other health services, except services described in subparagraphs (B), (C), and (D) of section 1395x(s)(2) of this title, such services are or were medically required;

.....

(E) in the case of comprehensive outpatient rehabilitation facility services, (i) such services are or were required because the individual needed skilled rehabilitation services, (ii) a plan for furnishing such services has been established and is periodically reviewed by a physician, and (iii) such services are or were furnished while the individual is or was under the care of a physician; and

(F) in the case of partial hospitalization services, (i) the individual would require inpatient psychiatric care in the absence of such services, (ii) an individualized, written plan for furnishing such services has been established by a physician and is reviewed periodically by a physician, and (iii) such services are or were furnished while the individual is or was under the care of a physician.

For purposes of this section, the term "provider of services" shall include a clinic, rehabilitation agency, or public health agency if, in the case of a clinic or rehabilitation agency, such clinic or agency meets the requirements of section 1395x(p)(4)(A) of this title (or meets the requirements of such section through the operation of section 1395x(g) of this title), or if, in the case of a public health agency, such agency meets the requirements of section 1395x(p)(4)(B) of this title (or meets the requirements of such section through the operation of section 1395x(g) of this title), but only with respect to the furnishing of outpatient physical therapy services (as therein defined) or (through the operation of section 1395x(g) of this title) with respect to the furnishing of outpatient occupational therapy services.

To the extent provided by regulations, the certification and recertification requirements of paragraph (2) shall be deemed satisfied where, at a later date, a physician makes a certification of the kind provided in subparagraph (A) or (B) of paragraph (2) (whichever would have applied), but only where such certification is accompanied by such medical and other evidence as may be required by such regulations. With respect to the physician certification required by paragraph (2) for home health services furnished to any individual by a home health agency (other than an agency which is a governmental entity) and with respect to the establishment and review of a plan for such services, the Secretary shall prescribe regulations which shall become effective no later than July 1, 1981, and which prohibit a physician who has a significant ownership interest in, or a significant financial or contractual relationship with, such home health agency from performing such certification and from establishing or reviewing such plan, except that such prohibition shall not apply with respect to a home health agency which is a sole community home health agency (as determined by the Secretary). For purposes of the preceding sentence, service by a physician as an uncompensated officer or director of a home health agency shall not constitute having a significant ownership interest in, or a significant financial or contractual relationship with, such agency. For purposes of paragraph (2)(A), an individual shall be considered to be "confined to his home" if the individual has a condition, due to an illness or injury, that restricts the ability of the individual to leave his or her home except with the assistance of another individual or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or her home is medically contraindicated. While an individual does not have to be bedridden to be considered "confined to his home", the condition of the individual should be such that there exists a normal inability to leave home, that leaving home requires a considerable and

taxing effort by the individual, and that absences of the individual from home are infrequent or of relatively short duration, or are attributable to the need to receive medical treatment.

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SOCIAL SECURITY ACT § 1861

42USC1395x

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part D--Miscellaneous Provisions

Sec. 1395x. Definitions

.....

(s) Medical and other health services

The term ``medical and other health services" means any of the following items or services:

(1) physicians' services;

(2)(A) services and supplies (including drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered) furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills;

(B) hospital services (including drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered) incident to physicians' services rendered to outpatients and partial hospitalization services incident to such services;

.....

(ee) Discharge planning process

(1) A discharge planning process of a hospital shall be considered sufficient if it is applicable to services furnished by the hospital to individuals entitled to benefits under this subchapter and if it meets the guidelines and standards established by the Secretary under paragraph (2).

(2) The Secretary shall develop guidelines and standards for the discharge planning process in order to ensure a timely and smooth transition to the most appropriate type of and setting for post-hospital or rehabilitative care. The guidelines and standards shall include the following:

(A) The hospital must identify, at an early stage of hospitalization, those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning.

(B) Hospitals must provide a discharge planning evaluation for patients identified under subparagraph (A) and for other patients upon the request of the patient, patient's representative, or patient's physician.

(C) Any discharge planning evaluation must be made on a timely basis to ensure that appropriate arrangements for post-hospital care will be made before discharge and to avoid unnecessary delays in discharge.

(D) A discharge planning evaluation must include an evaluation of a patient's likely need for appropriate post-hospital services, including hospice services, and the availability of those services, including the availability of home health services through individuals and entities that participate in the program under this subchapter and that serve the area in which the patient resides and that request to be listed by the hospital as available.

(E) The discharge planning evaluation must be included in the patient's medical record for use in establishing an appropriate discharge plan and the results of the evaluation must be discussed with the patient (or the patient's representative).

(F) Upon the request of a patient's physician, the hospital must arrange for the development and initial implementation of a discharge plan for the patient.

(G) Any discharge planning evaluation or discharge plan required under this paragraph must be developed by, or under the supervision of, a registered professional nurse, **social worker**, or other appropriately qualified personnel.

(H) Consistent with section 1395a of this title, the discharge plan shall--

(i) not specify or otherwise limit the qualified provider which may provide post-hospital home health services, and

(ii) identify (in a form and manner specified by the Secretary) any entity to whom the individual is referred in which the hospital has a disclosable financial interest (as specified by the Secretary consistent with section 1395cc(a)(1)(S) of this title) or which has such an interest in the hospital.

(3) With respect to a discharge plan for an individual who is enrolled with a Medicare+Choice organization under a Medicare+Choice plan and is furnished inpatient hospital services by a hospital under a contract with the organization--

(A) the discharge planning evaluation under paragraph (2)(D) is not required to include information on the availability of home health services through individuals and entities which do not have a contract with the organization; and

(B) notwithstanding subparagraph (H)(i) \10\, the plan may specify or limit the provider (or providers) of post-hospital home health services or other post-hospital services under the plan.

\10\ So in original. Probably should be ``paragraph (2)(H)(i)".

(ff) Partial hospitalization services

(1) The term ``partial hospitalization services" means the items and services described in paragraph (2) prescribed by a physician and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which plan sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan.

(2) The items and services described in this paragraph are--

(A) individual and group therapy with physicians or psychologists (or other **mental health professionals** to the extent authorized under State law),

(B) occupational therapy requiring the skills of a qualified occupational therapist,

(C) services of **social workers**, trained psychiatric nurses, and other staff trained to work with psychiatric patients,

(D) drugs and biologicals furnished for therapeutic purposes (which cannot, as determined in accordance with regulations, be self-administered),

(E) individualized activity therapies that are not primarily recreational or diversionary,

(F) family counseling (the primary purpose of which is treatment of the individual's condition),

(G) patient training and education (to the extent that training and educational activities are closely and clearly related to individual's care and treatment),

(H) diagnostic services, and

(I) such other items and services as the Secretary may provide (but in no event to include meals and transportation);

that are reasonable and necessary for the diagnosis or active treatment of the individual's condition, reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization, and furnished pursuant to such guidelines relating to frequency and duration of services as the Secretary shall by regulation establish (taking into account accepted norms of medical practice and the reasonable expectation of patient improvement).

(3)(A) A program described in this paragraph is a program which is furnished by a hospital to its outpatients or by a **community mental health center** (as defined in subparagraph (B)), and which is a distinct and organized intensive ambulatory treatment service offering less than 24-hour-daily care.

(B) For purposes of subparagraph (A), the term "community mental health center" means an entity--

(i) providing the services described in section 1916(c)(4) of the Public Health Service Act [42 U.S.C. 300x-4(c)(4)]; and

(ii) meeting applicable licensing or certification requirements for community mental health centers in the State in which it is located.

SOCIAL SECURITY ACT § 1866

42USC1395cc]

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part D--Miscellaneous Provisions

Sec. 1395cc. Agreements with providers of services

(e) "Provider of services" defined

For purposes of this section, the term "provider of services" shall include--

(1) a clinic, rehabilitation agency, or public health agency if, in the case of a clinic or rehabilitation agency, such clinic or agency meets the requirements of section 1395x(p)(4)(A) of this title (or meets the requirements of such section through the operation of section 1395x(g) of this title), or if, in the case of a public health agency, such agency meets the requirements of section 1395x(p)(4)(B) of this title (or meets the requirements of such section through the operation of section 1395x(g) of this title), but only with respect to the furnishing of outpatient physical therapy services (as therein defined) or (through the operation of section 1395x(g) of this title) with respect to the furnishing of outpatient occupational therapy services; and

(2) a **community mental health center** (as defined in section 1395x(ff)(3)(B) of this title), but only with respect to the furnishing of partial hospitalization services (as described in section 1395x(ff)(1) of this title).

PART 410--SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

Subpart A—General Provisions

.....

§ 410.2 Definitions.

As used in this part—

Community mental health center (CMHC) means an entity that—

- (1) Provides outpatient services, including specialized outpatient services for children, the elderly, individuals who are chronically mentally ill, and residents of its mental health service area who have been discharged from inpatient treatment at a mental health facility;
- (2) Provides 24-hour-a-day emergency care services;
- (3) Provides day treatment or other partial hospitalization services, or psychosocial rehabilitation services;
- (4) Provides screening for patients being considered for admission to State mental health facilities to determine the appropriateness of this admission; and
- (5) Meets applicable licensing or certification requirements for CMHCs in the State in which it is located.

Encounter means a direct personal contact between a patient and a physician, or other person who is authorized by State licensure law and, if applicable, by hospital or CAH staff bylaws, to order or furnish hospital services for diagnosis or treatment of the patient.

Nominal charge provider means a provider that furnishes services free of charge or at a nominal charge, and is either a public provider or another provider that (1) demonstrates to CMS's satisfaction that a significant portion of its patients are low-income; and (2) requests that payment for its services be determined accordingly.

Outpatient means a person who has not been admitted as an inpatient but who is registered on the hospital or CAH records as an outpatient and receives services (rather than supplies alone) directly from the hospital or CAH.

Partial hospitalization services means a distinct and organized intensive ambulatory treatment program that offers less than 24-hour daily care and furnishes the services described in § 410.43.

Participating refers to a hospital, CAH, SNF, HHA, CORF, or hospice that has in effect an agreement to participate in Medicare; or a clinic, rehabilitation agency, or public health agency that has a provider agreement to participate in Medicare but only for purposes of providing outpatient physical therapy, occupational therapy, or speech pathology services; or a CMHC that has in effect a similar agreement but only for purposes of providing partial hospitalization services, and *nonparticipating* refers to a hospital, CAH, SNF, HHA, CORF, hospice, clinic, rehabilitation agency, public health agency, or CMHC that does not have in effect a provider agreement to participate in Medicare.

[59 FR 6577, Feb. 11, 1994, as amended at 62 FR 46025, Aug. 29, 1997; 65 FR 18536, Apr. 7, 2000]

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Subpart B—Medical and Other Health Services

§ 410.10 Medical and other health services: Included services.

Subject to the conditions and limitations specified in this subpart, “medical and other health services” includes the following services:

- (a) Physicians' services.
- (b) Services and supplies furnished incident to a physician's professional services, of kinds that are commonly furnished in physicians' offices and are commonly either furnished without charge or included in the physicians' bills.
- (c) Services and supplies, including partial hospitalization services, that are incident to physician services and are furnished to outpatients by or under arrangements made by a hospital or a CAH.

(d) Diagnostic services furnished to outpatients by or under arrangements made by a hospital or a CAH if the services are services that the hospital or CAH ordinarily furnishes to its outpatients for diagnostic study.

(e) Diagnostic laboratory and X-ray tests (including diagnostic mammography that meets the conditions for coverage specified in § 410.34(b) of this subpart) and other diagnostic tests.

(f) X-ray therapy and other radiation therapy services.

(g) Medical supplies, appliances, and devices.

(h) Durable medical equipment.

(i) Ambulance services.

(j) Rural health clinic services.

(k) Home dialysis supplies and equipment; on or after July 1, 1991, epoetin (EPO) for home dialysis patients, and, on or after January 1, 1994, for dialysis patients, competent to use the drug; self-care home dialysis support services; and institutional dialysis services and supplies.

(l) Pneumococcal vaccinations.

(m) Outpatient physical therapy and speech pathology services.

(n) Cardiac pacemakers and pacemaker leads.

(o) Additional services furnished to enrollees of HMOs or CMPs, as described in § 410.58.

(p) Hepatitis B vaccine.

(q) Blood clotting factors for hemophilia patients competent to use these factors without medical or other supervision.

(r) Screening mammography services.

(s) Federally qualified health center services.

(t) Services of a certified registered nurse anesthetist or an anesthesiologist's assistant.

(u) Prescription drugs used in immunosuppressive therapy.

(v) Clinical psychologist services and services and supplies furnished as an incident to the services of a clinical psychologist, as provided in § 410.71.

(w) **Clinical social worker** services, as provided in § 410.73.

(x) Services of physicians and other practitioners furnished in or at the direction of an IHS or Indian tribal hospital or clinic.

[51 FR 41339, Nov. 14, 1986, as amended at 52 FR 27765, July 23, 1987; 55 FR 22790, June 4, 1990; 55 FR 53522, Dec. 31, 1990; 56 FR 8841, Mar. 1, 1991; 56 FR 43709, Sept. 4, 1991; 57 FR 24981, June 12, 1992; 57 FR 33896, July 31, 1992; 58 FR 30668, May 26, 1993; 59 FR 26959, May 25, 1994; 59 FR 49833, Sept. 30, 1994; 60 FR 8955, Feb. 16, 1995; 63 FR 20128, Apr. 23, 1998; 66 FR 55328, Nov. 1, 2001]

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§ 410.42 Limitations on coverage of certain services furnished to hospital outpatients.

(a) *General rule.* Except as provided in paragraph (b) of this section, Medicare Part B does not pay for any item or service that is furnished to a hospital outpatient (as defined in § 410.2) during an encounter (as defined in § 410.2) by an entity other than the hospital unless the hospital has an arrangement (as defined in § 409.3 of this chapter) with that entity to furnish that particular service to its patients. As used in this paragraph, the term “hospital” includes a CAH.

(b) *Exception.* The limitations stated in paragraph (a) of this section do not apply to the following services:

(1) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(2) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(3) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(4) Certified nurse mid-wife services, as defined in section 1861(gg) of the Act.

(5) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(6) Services of an anesthetist, as defined in § 410.69.

§ 410.43 Partial hospitalization services: Conditions and exclusions.

(a) Partial hospitalization services are services that—

- (1) Are reasonable and necessary for the diagnosis or active treatment of the individual's condition;
 - (2) Are reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization; and
 - (3) Include any of the following:
 - (i) Individual and group therapy with physicians or psychologists or **other mental health professionals** to the extent authorized under State law.
 - (ii) Occupational therapy requiring the skills of a qualified occupational therapist.
 - (iii) Services of **social workers**, trained psychiatric nurses, and other staff trained to work with psychiatric patients.
 - (iv) Drugs and biologicals furnished for therapeutic purposes, subject to the limitations specified in § 410.29.
 - (v) Individualized activity therapies that are not primarily recreational or diversionary.
 - (vi) Family counseling, the primary purpose of which is treatment of the individual's condition.
 - (vii) Patient training and education, to the extent the training and educational activities are closely and clearly related to the individual's care and treatment.
 - (viii) Diagnostic services.
 - (b) The following services are separately covered and not paid as partial hospitalization services:
 - (1) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.
 - (2) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.
 - (3) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.
 - (4) Qualified psychologist services, as defined in section 1861(ii) of the Act.
 - (5) Services furnished to SNF residents as defined in § 411.15(p) of this chapter.
- [59 FR 6577, Feb. 11, 1994, as amended at 65 FR 18536, Apr. 7, 2000]

§ 410.73 Clinical social worker services.

- (a) *Definition: **clinical social worker**.* For purposes of this part, a clinical social worker is defined as an individual who—
 - (1) Possesses a master's or doctor's degree in social work;
 - (2) After obtaining the degree, has performed at least 2 years of supervised clinical social work; and
 - (3) Either is licensed or certified as a **clinical social worker** by the State in which the services are performed or, in the case of an individual in a State that does not provide for licensure or certification as a **clinical social worker** —
 - (i) Is licensed or certified at the highest level of practice provided by the laws of the State in which the services are performed; and
 - (ii) Has completed at least 2 years or 3,000 hours of post master's degree supervised **clinical social work** practice under the supervision of a master's degree level **social worker** in an appropriate setting such as a hospital, SNF, or clinic.
- (b) *Covered clinical social worker services.* Medicare Part B covers **clinical social worker** services.
 - (1) *Definition.* "**Clinical social worker services**" means, except as specified in paragraph (b)(2) of this section, the services of a clinical social worker furnished for the diagnosis and treatment of mental illness that the clinical social worker is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which the services are performed. The services must be of a type that would be covered if they were furnished by a physician or as an incident to a physician's professional service and must meet the requirements of this section.
 - (2) *Exception.* The following services are **not clinical social worker** services for purposes of billing Medicare Part B:
 - (i) Services furnished by a **clinical social worker** to an inpatient of a Medicare-participating hospital.

- (ii) Services furnished by a **clinical social worker** to an inpatient of a Medicare-participating SNF.
- (iii) Services furnished by a **clinical social worker** to a patient in a Medicare-participating dialysis facility if the services are those required by the conditions for coverage for ESRD facilities under §405.2163 of this chapter.
- (c) *Agreement to consult.* A **clinical social worker** must comply with the consultation requirements set forth at § 410.71(f) (reading “clinical psychologist” as “**clinical social worker**”).
- (d) *Prohibited billing.* (1) A **clinical social worker** may not bill Medicare for the services specified in paragraph (b)(2) of this section.
- (2) A **clinical social worker** or an attending or primary care physician may not bill Medicare or the beneficiary for the consultation that is required under paragraph (c) of this section.

[63 FR 20128, Apr. 23, 1998]

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Subpart E—Community Mental Health Centers (CMHCs) Providing Partial Hospitalization Services

§ 410.110 Requirements for coverage of partial hospitalization services by CMHCs.

Medicare part B covers partial hospitalization services furnished by or under arrangements made by a CMHC if they are provided by a CMHC as defined in § 410.2 that has in effect a provider agreement under part 489 of this chapter and if the services are—

- (a) Prescribed by a physician and furnished under the general supervision of a physician;
- (b) Subject to certification by a physician in accordance with § 424.24(e)(1) of this subchapter; and
- (c) Furnished under a plan of treatment that meets the requirements of § 424.24(e)(2) of this subchapter.

[59 FR 6577, Feb. 11, 1994]

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§ 410.172 Payment for partial hospitalization services in CMHCs: Conditions.

Medicare Part B pays for partial hospitalization services furnished in a CMHC on behalf of an individual only if the following conditions are met:

- (a) The CMHC files a written request for payment on the CMS form 1450 and in the manner prescribed by CMS; and
- (b) The services are furnished in accordance with the requirements described in § 410.110.

[59 FR 6578, Feb. 11, 1994]

PART 424--CONDITIONS FOR MEDICARE PAYMENT

§ 424.24 Requirements for medical and other health services furnished by providers under Medicare Part B.

(a) *Exempted services.* Certification is not required for the following: (1) Hospital services and supplies incident to physicians' services furnished to outpatients. The exemption applies to drugs and biologicals that cannot be self-administered, but not to partial hospitalization services, as set forth in paragraph (e) of this section.

(2) Outpatient hospital diagnostic services, including necessary drugs and biologicals, ordinarily furnished or arranged for by a hospital for the purpose of diagnostic study.

(b) *General rule.* Medicare Part B pays for medical and other health services furnished by providers (and not exempted under paragraph (a) of this section) only if a physician certifies the content specified in paragraph (c)(1), (c)(4) or (e)(1) of this section, as appropriate.

(c) *Outpatient physical therapy and speech-language pathology services—(1) Content of certification.* (i) The individual needs, or needed, physical therapy or speech pathology services.

(ii) The services were furnished while the individual was under the care of a physician, nurse practitioner, clinical nurse specialist, or physician assistant.

(iii) The services were furnished under a plan of treatment that meets the requirements of § 410.61 of this chapter.

(2) *Timing.* The certification statement must be obtained at the time the plan of treatment is established, or as soon thereafter as possible.

(3) *Signature.* (i) If the plan of treatment is established by a physician, nurse practitioner, clinical nurse specialist, or physician assistant, the certification must be signed by that physician or nonphysician practitioner.

(ii) If the plan of treatment is established by a physical therapist or speech-language pathologist, the certification must be signed by a physician or by a nurse practitioner, clinical nurse specialist, or physician assistant who has knowledge of the case.

(4) *Recertification—(i) Timing.*

Recertification statements are required at least every 30 days and must be signed by the physician, nurse practitioner, clinical nurse specialist, or physician assistant who reviews the plan of treatment.

(ii) *Content.* The recertification statement must indicate the continuing need for physical therapy or speech-language pathology services and an estimate of how much longer the services will be needed.

(iii) *Signature.* Recertifications must be signed by the physician, nurse practitioner, clinical nurse specialist, or physician assistant who reviews the plan of treatment.

(d) [Reserved]

(e) *Partial hospitalization services: Content of certification and plan of treatment*

requirements—(1) Content of certification.

(i) The individual would require inpatient psychiatric care if the partial hospitalization services were not provided.

(ii) The services are or were furnished while the individual was under the care of a physician.

(iii) The services were furnished under a written plan of treatment that meets the requirements of paragraph (e)(2) of this section.

(2) *Plan of treatment requirements.* (i) The plan is an individualized plan that is established and is periodically reviewed by a physician in consultation with appropriate staff participating in the program, and that sets forth—

(A) The physician's diagnosis;

(B) The type, amount, duration, and frequency of the services; and

(C) The treatment goals under the plan.

(ii) The physician determines the frequency and duration of the services taking into account accepted norms of medical practice and a reasonable expectation of improvement in the patient's condition.

(3) *Recertification requirements.*

(i) *Signature.* The physician recertification must be signed by a physician who is treating

the patient and has knowledge of the patient's response to treatment.

(ii) *Timing*. The first recertification is required as of the 18th day of partial hospitalization services. Subsequent recertifications are required at intervals established by the provider, but no less frequently than every 30 days.

(iii) *Content*. The recertification must specify that the patient would otherwise require inpatient psychiatric care in the absence of continued stay in the partial hospitalization program and describe the following:

(A) The patient's response to the therapeutic interventions provided by the partial hospitalization program.

(B) The patient's psychiatric symptoms that continue to place the patient at risk of hospitalization.

(C) Treatment goals for coordination of services to facilitate discharge from the partial hospitalization program.

(f) *All other covered medical and other health services furnished by providers*—(1) *Content of certification*. The services were medically necessary,

(2) *Signature*. The certificate must be signed by a physician, nurse practitioner, clinical nurse specialist, or physician assistant who has knowledge of the case.

(3) *Timing*. The physician, nurse practitioner, clinical nurse specialist, or physician assistant may provide certification at the time the services are furnished or, if services are provided on a continuing basis, either at the beginning or at the end of a series of visits.

(4) *Recertification*. Recertification of continued need for services is not required.

[53 FR 6638, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988; 56 FR 8845, 8853, Mar. 1, 1991; 63 FR 58912, Nov. 2, 1998; 65 FR 18548, Apr. 7, 2000]

Omnibus Budget Reconciliation Act of 1987

CONFERENCE REPORT 100-495

(b) Partial Hospitalization Coverage.--Medicare authorizes coverage for hospital services incident to physicians' services provided to hospital outpatients. There is no specific authorization for a partial hospitalization benefit, under which psychiatric patients can be treated in a hospital on an outpatient basis.

Under program guidelines, hospital-based distinct and organized care programs can provide care for less than 24 hours a day. In general, to be covered under Medicare, the services must be incident to a physician's service and reasonable and necessary for the diagnosis and treatment of the patient's condition.

House bill

No provision.

Senate amendment

(a) Outpatient Services Under Part B.--Increases the limit on recognized charges to \$1,375 per year; thus the maximum payment is \$1,100. Brief office visits (as defined by the Secretary) for the sole purpose of prescribing or monitoring prescription drugs used in the treatment of such disorders are not included for purposes of the limit.

(b) Partial Hospitalization Coverage.--

(1) Includes 'partial hospitalization services incident to physicians' services within the definition of covered Part B services. Partial hospitalization services means the items and services described ****2313x1382 *636** under (2) prescribed by a physician and provided under a program described in (3) under the supervision of a physician pursuant to an individualized written plan of treatment established and periodically reviewed by a physician in consultation with appropriate staff participating in the program. The plan must state the physician's diagnosis; type, amount, frequency and duration of items and services provided under the plan; and treatment goals.

(2) Specifies that the items and services are: (A) individuals and group therapy with physicians, psychologists (or other **mental health professionals** to the extent authorized under State law); (B) occupational therapy requiring the skills of a qualified occupational therapist; (C) services of **social workers**, trained psychiatric nurses and other staff trained to work with psychiatric patients; (D) drugs and biologicals furnished for therapeutic purposes (which cannot be self-administered); (E) individualized activity therapies that are not primarily recreational or diversionary; (F) family counseling (the primary purpose of which is to treat the individual's condition); (G) patient training and education (to the extent that training and educational activities are closely related to the individual's care and treatment; (H) diagnostic services; and (I) such other items and services as the Secretary may provide (not including meals and transportation). These items must be reasonable and necessary for the diagnosis and treatment of the individual's condition, reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization. They must be furnished pursuant to such guidelines relating to frequency and duration as the Secretary may establish taking into account accepted norms of medical practice and reasonable expectation of patient improvement.

(3) Specifies that a described program is a hospital-based or hospital-affiliated program which is a distinct and organized intensive ambulatory treatment service offering less than 24-hour daily care.

(4) Requires physician certification, and recertification where such services are required over a period of time, that the individual would require inpatient psychiatric care in the absence of such services; an individualized, written plan for furnishing such services has been established and reviewed periodically by a physician, and the services are or were furnished while the patient was

under a physician's care.

(5) Specifies that partial hospitalization services not directly provided by a physician are not subject to the Part B limit on outpatient mental health services.

Requires the Secretary to implement this provision so as to insure that there is no additional cost to the Medicare program.

Effective date.--(a) Applies with respect to calendar years beginning on or after January 1, 1988, (b) Enactment.

Conference agreement

...

(b) Partial Hospitalization.--The conference agreement includes the Senate amendment with an amendment limiting application of the provision to hospital-based or hospital-affiliated providers as defined by the Secretary.

22. Coverage of Certified Nurse-Midwife Services (Section 4027 of Senate Amendment)

RURAL HEALTH CLINICS – CLINICAL SOCIAL WORK SERVICES/CLINICAL SOCIAL WORKERS

Section 6213 of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89), P.L. 101-239, amended Section 1861(aa)(1)(B) of the Social Security Act by adding coverage for clinical social workers in Medicare-certified rural health clinics (RHCs) effective October 1, 1989. Reimbursement for clinical social worker services is also extended to cover Medicaid beneficiaries in this setting because all RHCs certified under Medicare are automatically certified under Medicaid.

In 1977, Congress passed the Rural Health Clinic Act (P.L. 95-210), which amended the Social Security Act to allow for direct Medicare and Medicaid payments to clinics in medically underserved areas. The initial law provided for reimbursement to physician assistants and nurse practitioners even when a physician is not present. However, a physician must be available, even if not on-site, in a supervisory capacity.

Specifically, Section 1861(aa)(2) of the Social Security Act defines a rural health clinic as a facility that is located in an area that is not urbanized and is designated as an area with a shortage of health manpower or services; has filed an agreement with the Secretary of the U.S. Department of Health and Human Services by which it agrees not to charge any individual or other person for items or services they are entitled to under law except for any deductible or coinsurance; employs a physician, physician assistant, or nurse practitioner; and is not a rehabilitation agency or a facility that is primarily for the care and treatment of mental diseases. (See the statutory citation for the complete definition of rural health clinic.)

With the passage of OBRA '89, clinical social worker services were added to what is referred to as the "core services" for RHCs. Clinical psychologists were included in the law in OBRA '87. The law does not mandate that RHCs provide mental health services, but it does provide for reimbursement for services of, and services and supplies that are incident to, clinical social workers and clinical psychologists. (See "Outpatient Mental Health Services" for the discussion on the use of the term "incident to.")

The OBRA '89 amendment refers to Section 1861(hh)(1) of the statute for the definition of clinical social worker. This is the same definition used for Medicare Part B outpatient mental health benefits. Specifically, the definition requires that a clinical social worker have a master's or doctoral degree in social work, at least two years of supervised clinical social work practice, and licensing or certification as a clinical social worker in the state in which the services are being performed. In the states that do not provide for licensure or certification, the individual must have completed two years or 3,000 hours of post-master's supervised clinical social work in an appropriate setting, and meet other criteria that may be established by the Secretary of the U.S. Department of Health and Human Services. (See "Outpatient Mental Health Services" for the OBRA '89 citation defining clinical social worker.)

Payment for rural health clinic services varies according to whether it is a "provider clinic" or an "independent clinic." A provider clinic, according to the regulation (42 CFR 405.2425(a)), is "an integral and subordinate part of a hospital, skilled nursing facility or home health agency participating in Medicare (i.e. a provider of services)." Provider-based clinics are reimbursed by Medicare on the basis of "reasonable cost" principles.

"Independent clinics," (42 CFR 405.2425(b)) a category most RHCs fall into, are paid on the basis of "costs which are reasonable and related to the cost of furnishing such services..." (Social Security Act, Section 1833(aX3)). Reimbursement is based on an all-inclusive rate for each beneficiary visit for covered services. The all-inclusive rate, as provided for in the regulations (42 CFR 405.2426), is determined by the carriers for each RHC on the basis of actual costs and number of visits at the beginning of each reporting period. The RHC is reimbursed per visit,

regardless of which health care staff person or how many staff persons are involved. The Medicare payment, for example, for a physician assistant, a nurse practitioner, or a clinical social worker, would appear to be the same, except that payment for clinical social work services are subject to the mental health payment limit described below. The current maximum fee per visit, effective January 1, 2005, is \$70.78, which is adjusted annually based on the Medicare Economic Index.¹¹

As noted above, the outpatient mental health payment limit would apply to reimbursement of clinical social work services under Medicare. This payment limit pertains to the treatment of mental, psychoneurotic, and personality disorders on an outpatient basis in a calendar year. It does not apply to diagnostic services. The payment limit is 62.5 percent of total expenses. In addition, Medicare Part B pays only 80 percent of covered costs with the beneficiary required to pay a 20 percent co-payment. Because the 62.5 percent applies to the overall expenses, the beneficiary is paying what amounts to a 50 percent co-payment. Although extending coverage to clinical social workers in RHCs provides needed mental health services to rural populations, the payment for such services clearly is very limited. It is possible, however, that where clinical social workers provide services as part of a contractual arrangement with an RHC, alternative reimbursement mechanisms could be used.

It is also important to note that the outpatient mental health payment limit, however, does not apply to Medicaid beneficiaries. Section 1902(ax13)(E) of the statute (see citation) provides for the payment of RHCs under Medicaid at 100 percent of the Medicare all-inclusive payment rate for those RHC services payable under Medicare.

The OBRA '89 amendment to the statute also provides for coverage of services and supplies that are incident to clinical social work services. In general, services and supplies that are incident to the services of a clinical social worker would typically be those that are furnished in a clinical social worker's office or a clinic without charge or as charges included as part of a social worker's bill. Such services would generally be part of a clinical social worker's professional services carried out in the course of diagnosis or treatment. Such services, if delivered by someone else, would have to be under the direct supervision of a clinical social worker.

¹¹ U.S. Department of Health and Human Services (2004) Pub. 100-04 Medicare claims processing [Online]. Retrieved from http://www.cms.hhs.gov/manuals/pm_trans/R390CP.pdf on May 26, 2005.

SOCIAL SECURITY ACT § 711

42USC912

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER VII--ADMINISTRATION

Sec. 912. Office of Rural Health Policy

(a) There shall be established in the Department of Health and Human Services (in this section referred to as the ``Department'') an Office of Rural Health Policy (in this section referred to as the ``Office''). The Office shall be headed by a Director, who shall advise the Secretary on the effects of current policies and proposed statutory, regulatory, administrative, and budgetary changes in the programs established under subchapters XVIII and XIX of this chapter on the financial viability of small rural hospitals, the ability of rural areas (and rural hospitals in particular) to attract and retain physicians and other health professionals, and access to (and the quality of) health care in rural areas.

(b) In addition to advising the Secretary with respect to the matters specified in subsection (a) of this section, the Director, through the Office, shall--

(1) oversee compliance with the requirements of section 1302(b) of this title and section 4403 of the Omnibus Budget Reconciliation Act of 1987 (as such section pertains to rural health issues),

(2) establish and maintain a clearinghouse for collecting and disseminating information on--

(A) rural health care issues, including **rural mental health**, rural infant mortality prevention, and rural occupational safety and preventive health promotion,

(B) research findings relating to rural health care, and

(C) innovative approaches to the delivery of health care in rural areas, including programs providing **community-based mental health services**, pre-natal and infant care services, and rural occupational safety and preventive health education and promotion,

(3) coordinate the activities within the Department that relate to rural health care, and

(4) provide information to the Secretary and others in the Department with respect to the activities, of other Federal departments and agencies, that relate to rural health care, including activities relating to **rural mental health**, rural infant mortality, and rural occupational safety and preventive health promotion.

SOCIAL SECURITY ACT § 1831

42USC1395j

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part B--Supplementary Medical Insurance Benefits for Aged and Disabled

Sec. 1395j. Establishment of supplementary medical insurance program for aged and disabled

There is hereby established a voluntary insurance program to provide medical insurance benefits in accordance with the provisions of this part for aged and disabled individuals who elect

to enroll under such program, to be financed from premium payments by enrollees together with contributions from funds appropriated by the Federal Government.

SOCIAL SECURITY ACT § 1832

42USC1395k

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part B--Supplementary Medical Insurance Benefits for Aged and Disabled

Sec. 1395k. Scope of benefits; extension of coverage of immunosuppressive drugs; definitions

(a) Scope of benefits

The benefits provided to an individual by the insurance program established by this part shall consist of--

(1) entitlement to have payment made to him or on his behalf (subject to the provisions of this part) for medical and other health services, except those described in subparagraphs (B) and (D) of paragraph (2) and subparagraphs (E) and (F) of section 1395u(b)(6) of this title; and

(2) entitlement to have payment made on his behalf (subject to the provisions of this part) for--

(A) home health services (other than items described in subparagraph (G) or subparagraph (I));

(B) medical and other health services (other than items described in subparagraph (G) or subparagraph (I)) furnished by a provider of services or by others under arrangement with them made by a provider of services, excluding--

(i) physician services except where furnished by--

(I) a resident or intern of a hospital, or

(II) a physician to a patient in a hospital which has a teaching program approved as specified in paragraph (6) of section 1395x(b) of this title (including services in conjunction with the teaching programs of such hospital whether or not such patient is an inpatient of such hospital) where the conditions specified in paragraph (7) of such section are met,

(ii) services for which payment may be made pursuant to section 1395n(b)(2) of this title,

(iii) services described by section 1395x(s)(2)(K)(i) of this title, certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist; \1\

\1\ So in original. The semicolon probably should be a comma.

(iv) services of a nurse practitioner or clinical nurse specialist but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services; and \2\

\2\ So in original. The word ``and" probably should not appear.

(C) outpatient physical therapy services (other than services to which the second sentence of section 1395x(p) of this title applies) and outpatient occupational therapy services (other than services to which such sentence applies through the operation of section 1395x(g) of this title);

(D)(i) rural health clinic services and (ii) Federally qualified health center services;

(E) comprehensive outpatient rehabilitation facility services;

SOCIAL SECURITY ACT § 1833

42USC1395I

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part B--Supplementary Medical Insurance Benefits for Aged and Disabled

Sec. 1395I. Payment of benefits

(a) Amounts

Except as provided in section 1395mm of this title, and subject to the succeeding provisions of this section, there shall be paid from the Federal Supplementary Medical Insurance Trust Fund, in the case of each individual who is covered under the insurance program established by this part and incurs expenses for services with respect to which benefits are payable under this part, amounts equal to--

.....

(b) Deductible provision

Before applying subsection (a) of this section with respect to expenses incurred by an individual during any calendar year, the total amount of the expenses incurred by such individual during such year (which would, except for this subsection, constitute incurred expenses from which benefits payable under subsection (a) of this section are determinable) shall be reduced by a deductible of \$75 for calendar years before 1991 and \$100 for 1991 and subsequent years; except that (1) such total amount shall not include expenses incurred for items and services described in section 1395x(s)(10)(A) of this title, (2) such deductible shall not apply with respect to home health services (other than a covered osteoporosis drug (as defined in section 1395x(kk) of this title)), (3) such deductible shall not apply with respect to clinical diagnostic laboratory tests for which payment is made under this part (A) under subsection (a)(1)(D)(i) or (a)(2)(D)(i) of this section on an assignment-related basis, or to a provider having an agreement under section 1395cc of this title, or (B) on the basis of a negotiated rate determined under subsection (h)(6) of

this section, (4) such deductible shall not apply to Federally qualified health center services. (5) such

deductible shall not apply with respect to screening mammography (as described in section 1395x(jj) of this title), and (6) such deductible shall not apply with respect to screening pap smear and screening pelvic exam (as described in section 1395x(nn) of this title). The total amount of the expenses incurred by an individual as determined under the preceding sentence shall, after the reduction specified in such sentence, be further reduced by an amount equal to the expenses incurred for the first three pints of whole blood (or equivalent quantities of packed red blood cells, as defined under regulations) furnished to the individual during the calendar year, except that such deductible for such blood shall in accordance with regulations be appropriately

reduced to the extent that there has been a replacement of such blood or equivalent quantities of packed red blood cells, as so defined); and for such purposes blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual shall be deemed replaced when the institution or other person furnishing such blood (or such equivalent quantities of packed red blood cells, as so defined) is given one pint of blood for each pint of blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual with respect to which a deduction is made under this sentence. The deductible under the previous sentence for blood or blood cells furnished an individual in a year shall be reduced to the extent that a deductible has been imposed under section 1395e(a)(2) of this title to blood or blood cells furnished the individual in the year.

(c) Mental disorders

Notwithstanding any other provision of this part, with respect to expenses incurred in any calendar year in connection with the treatment of mental, psychoneurotic, and personality disorders of an individual who is not an inpatient of a hospital at the time such expenses are incurred, there shall be considered as incurred expenses for purposes of subsections (a) and (b) of this section only 62½ percent of such expenses. For purposes of this subsection, the term "treatment" does not include brief office visits (as defined by the Secretary) for the sole purpose of monitoring or changing drug prescriptions used in the treatment of such disorders or partial hospitalization services that are not directly provided by a physician.

SOCIAL SECURITY ACT § 1861

42USC1395x

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part D--Miscellaneous Provisions

Sec. 1395x. Definitions

For purposes of this subchapter--

(s) Medical and other health services

The term "medical and other health services" means any of the following items or services:

...

(E) rural health clinic services and Federally qualified health center services;

.....

(aa) Rural health clinic services and Federally qualified health center services

(1) The term "rural health clinic services" means--

(A) physicians' services and such services and supplies as are covered under subsection (s)(2)(A) of this section if furnished as an incident to a physician's professional service and items and services described in subsection (s)(10) of this section,

(B) such services furnished by a physician assistant or a nurse practitioner (as defined in paragraph (5)), by a clinical psychologist (as defined by the Secretary) or by a **clinical social worker** (as defined in subsection (hh)(1) of this section), and such services and supplies furnished as an incident to his service as would otherwise be covered if furnished by a physician or as an incident to a physician's service, and

\8\ So in original.

(C) in the case of a rural health clinic located in an area in which there exists a shortage of home health agencies, part-time or intermittent nursing care and related medical supplies (other than drugs and biologicals) furnished by a registered professional nurse or licensed practical nurse to a homebound individual under a written plan of treatment (i) established and periodically reviewed by a physician described in paragraph (2)(B), or (ii) established by a nurse practitioner or physician assistant and periodically reviewed and approved by a physician described in paragraph (2)(B), when furnished to an individual as an outpatient of a rural health clinic.

(2) The term "rural health clinic" means a facility which--

(A) is primarily engaged in furnishing to outpatients services described in subparagraphs (A) and (B) of paragraph (1);

(B) in the case of a facility which is not a physician-directed clinic, has an arrangement (consistent with the provisions of State and local law relative to the practice, performance, and delivery of health services) with one or more physicians (as defined in subsection (r)(1)) of this section under which provision is made for the periodic review by such physicians of covered services furnished by physician assistants and nurse practitioners, the supervision and guidance by such physicians of physician assistants and nurse practitioners, the preparation by such physicians of such medical orders for care and treatment of clinic patients as may be necessary, and the availability of such physicians for such referral of and consultation for patients as is necessary and for advice and assistance in the management of medical emergencies; and, in the case of a physician-directed clinic, has one or more of its staff physicians perform the activities accomplished through such an arrangement;

(C) maintains clinical records on all patients;

(D) has arrangements with one or more hospitals, having agreements in effect under section 1395cc of this title, for the referral and admission of patients requiring inpatient services or such diagnostic or other specialized services as are not available at the clinic;

(E) has written policies, which are developed with the advice of (and with provision for review of such policies from time to time by) a group of professional personnel, including one or more physicians and one or more physician assistants or nurse practitioners, to govern those services described in paragraph (1) which it furnishes;

(F) has a physician, physician assistant, or nurse practitioner responsible for the execution of policies described in subparagraph (E) and relating to the provision of the clinic's services;

(G) directly provides routine diagnostic services, including clinical laboratory services, as prescribed in regulations by the Secretary, and has prompt access to additional diagnostic services from facilities meeting requirements under this subchapter;

(H) in compliance with State and Federal law, has available for administering to patients of the clinic at least such drugs and biologicals as are determined by the Secretary to be necessary for the treatment of emergency cases (as defined in regulations) and has appropriate procedures or arrangements for storing, administering, and dispensing any drugs and biologicals;

(I) has a quality assessment and performance improvement program, and appropriate procedures for review of utilization of clinic services, as the Secretary may specify;

(J) has a nurse practitioner, a physician assistant, or a certified nurse-midwife (as defined in subsection (gg) of this section) available to furnish patient care services not less than 50 percent of the time the clinic operates; and

(K) meets such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are furnished services by the clinic.

For the purposes of this subchapter, such term includes only a facility which (i) is located in an area that is not an urbanized area (as defined by the Bureau of the Census) and in which there are insufficient numbers of needed health care practitioners (as determined by the Secretary), and that, within the previous 3-year period, has been designated by the chief executive officer of the State and certified by the Secretary as an area with a shortage of personal health services or designated by the Secretary either (I) as an area with a shortage of personal health services under section 330(b)(3) \9\ or 1302(7) [42 U.S.C. 300e-1 (7)] of the Public Health Service Act, (II) as a health professional shortage area described in section 332(a)(1)(A) of that Act [42 U.S.C. 254e(a)(1)(A)] because of its shortage of primary medical care manpower, (III) as a high impact area described in section 329(a)(5) \9\ of that Act, or (IV) as an area which includes a population group which the Secretary determines has a health manpower shortage under section 332(a)(1)(B) of that Act [42 U.S.C. 254e(a)(1)(B)], (ii) has filed an agreement with the Secretary by which it agrees not to charge any individual or other person for items or services for which such individual is entitled to have payment made under this subchapter, except for the amount of any deductible or coinsurance amount imposed with respect to such items or services (not in excess of the amount customarily charged for such items and services by such clinic), pursuant to subsections (a) and (b) of section 1395l of this title, (iii) employs a physician assistant or nurse practitioner, and (iv) is not a rehabilitation agency or a facility which is primarily for the care and treatment of mental diseases. A facility that is in operation and qualifies as a rural health clinic under this subchapter or subchapter XIX of this chapter and that subsequently fails to satisfy the requirement of clause (i) shall be considered, for purposes of this subchapter and subchapter XIX of this chapter, as still satisfying the requirement of such clause if it is determined, in accordance with criteria established by the Secretary in regulations, to be essential to the delivery of primary care services that would otherwise be unavailable in the geographic area served by the clinic. If a State agency has determined under section 1395aa(a) of this title that a facility is a rural health clinic and the facility has applied to the Secretary for approval as such a clinic, the Secretary shall notify the facility of the Secretary's approval or disapproval not later than 60 days after the date of the State agency determination or the application (whichever is later).

\9\ See References in Text note below.

(3) The term ``Federally qualified health center services" means--

(A) services of the type described in subparagraphs (A) through (C) of paragraph (1), and

(B) preventive primary health services that a center is required to provide under sections

329, 330, and 340 \9\ of the Public Health Service Act,

when furnished to an individual as an outpatient of a Federally qualified health center and, for this purpose, any reference to a rural health clinic or a physician described in paragraph (2)(B) is deemed a reference to a Federally qualified health center or a physician at the center, respectively.

(4) The term ``Federally qualified health center" means an entity which--

(A)(i) is receiving a grant under section 330 (other than subsection (h)) of the Public Health Service Act [42 U.S.C. 254b], or -

(ii)(I) is receiving funding from such a grant under a contract with the recipient of such a grant, and (II) meets the requirements to receive a grant under section 330 (other than subsection (h)) of such Act [42 U.S.C. 254b];

(B) based on the recommendation of the Health Resources and Services Administration within the Public Health Service, is determined by the Secretary to meet the requirements for receiving such a grant;

(C) was treated by the Secretary, for purposes of part B of this subchapter, as a - comprehensive Federally funded health center as of January 1, 1990; or -

(D) is an outpatient health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act [25 U.S.C. 450f et seq.] or by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act [25 U.S.C. 1651 et seq.].

(5)(A) The term ``physician assistant" and the term ``nurse practitioner" mean, for purposes of this subchapter, a physician assistant or nurse practitioner who performs such services as such individual is legally authorized to perform (in the State in which the individual performs such services) in accordance with State law (or the State regulatory mechanism provided by State law), and who meets such training, education, and experience requirements (or any combination thereof) as the Secretary may prescribe in regulations.

(B) The term ``clinical nurse specialist" means, for purposes of this subchapter, an individual who--

(i) is a registered nurse and is licensed to practice nursing in the State in which the clinical nurse specialist services are performed; and

(ii) holds a master's degree in a defined clinical area of nursing from an accredited - educational institution. -

(6) The term ``collaboration" means a process in which a nurse practitioner works with a physician to deliver health care services within the scope of the practitioner's professional expertise, with medical direction and appropriate supervision as provided for in jointly developed guidelines or other mechanisms as defined by the law of the State in which the services are performed.

(7)(A) The Secretary shall waive for a 1-year period the requirements of paragraph (2) that a rural health clinic employ a physician assistant, nurse practitioner or certified nurse midwife or that such clinic require such providers to furnish services at least 50 percent of the time that the clinic operates for any facility that requests such waiver if the facility demonstrates that the facility has been unable, despite reasonable efforts, to hire a physician assistant, nurse practitioner, or certified nurse-midwife in the previous 90-day period.

(B) The Secretary may not grant such a waiver under subparagraph (A) to a facility if the request for the waiver is made less than 6 months after the date of the expiration of any previous such waiver for the facility, or if the facility has not yet been determined to meet the requirements (including subparagraph (J) of the first sentence of paragraph (2)) of a rural health clinic.

(C) A waiver which is requested under this paragraph shall be deemed granted unless such request is denied by the Secretary within 60 days after the date such request is received.

SOCIAL SECURITY ACT § 1862

42USC1395y

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part D--Miscellaneous Provisions

Sec. 1395y. Exclusions from coverage and medicare as secondary payer

(a) Items or services specifically excluded

Notwithstanding any other provision of this subchapter, no payment may be made under part A or part B of this subchapter for any expenses incurred for items or services--

(1)(A) which, except for items and services described in a succeeding subparagraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,

(B) in the case of items and services described in section 1395x(s)(10) of this title, which are not reasonable and necessary for the prevention of illness,

(C) in the case of hospice care, which are not reasonable and necessary for the palliation or management of terminal illness,

(D) in the case of clinical care items and services provided with the concurrence of the Secretary and with respect to research and experimentation conducted by, or under contract with, the Medicare Payment Advisory Commission or the Secretary, which are not reasonable and necessary to carry out the purposes of section 1395ww(e)(6) of this title,\1\

\1\ See References in Text note below.

(E) in the case of research conducted pursuant to section 1320b-12 of this title, which is not reasonable and necessary to carry out the purposes of that section,

(F) in the case of screening mammography, which is performed more frequently than is covered under section 1395m(c)(2) of this title or which is not conducted by a facility described in section 1395m(c)(1)(B) of this title, and, in the case of screening pap smear and screening pelvic exam, which is performed more frequently than is provided under section 1395x(nn) of this title,

(G) in the case of prostate cancer screening tests (as defined in section 1395x(oo) of this title), which are performed more frequently than is covered under such section,

(H) in the case of colorectal cancer screening tests, which are performed more frequently than is covered under section 1395m(d) of this title, and

(I) the frequency and duration of home health services which are in excess of normative guidelines that the Secretary shall establish by regulation;

(2) for which the individual furnished such items or services has no legal obligation to pay, and which no other person (by reason of such individual's membership in a prepayment plan or otherwise) has a legal obligation to provide or pay for, except in the case of Federally qualified health center services;

(3) which are paid for directly or indirectly by a governmental entity (other than under this chapter and other than under a health benefits or insurance plan established for employees of such an entity), except in the case of rural health clinic services, as defined in section

1395x(aa)(1) of this title, \2\ in the case of Federally qualified health center services, as defined in section 1395x(aa)(3) of this title, and in such other cases as the Secretary may specify;

\2\ So in original.

(4) which are not provided within the United States (except for inpatient hospital services furnished outside the United States under the conditions described in section 1395f(f) of this title and, subject to such conditions, limitations, and requirements as are provided under or pursuant to this subchapter, physicians' services and ambulance services furnished an individual in conjunction with such inpatient hospital services but only for the period during which such inpatient hospital services were furnished);

(5) which are required as a result of war, or of an act of war, occurring after the effective date of such individual's current coverage under such part;

(6) which constitute personal comfort items (except, in the case of hospice care, as is - otherwise permitted under paragraph (1)(C)); -

(7) where such expenses are for routine physical checkups, eyeglasses (other than eyewear described in section 1395x(s)(8) of this title) or eye examinations for the purpose of prescribing, fitting, or changing eyeglasses, procedures performed (during the course of any eye examination) to determine the refractive state of the eyes, hearing aids or examinations therefor, or immunizations (except as otherwise allowed under section 1395x(s)(10) of this title and subparagraph (B), (F), (G), or (H) of paragraph (1));

(8) where such expenses are for orthopedic shoes or other supportive devices for the feet, other than shoes furnished pursuant to section 1395x(s)(12) of this title;

(9) where such expenses are for custodial care (except, in the case of hospice care, as is otherwise permitted under paragraph (1)(C));

(10) where such expenses are for cosmetic surgery or are incurred in connection therewith, except as required for the prompt repair of accidental injury or for improvement of the functioning of a malformed body member;

(11) where such expenses constitute charges imposed by immediate relatives of such - individual or members of his household; -

(12) where such expenses are for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, except that payment may be made under part A of this subchapter in the case of inpatient hospital services in connection with the provision of such dental services if the individual, because of his underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services;

(13) where such expenses are for--

(A) the treatment of flat foot conditions and the prescription of supportive devices therefor,

(B) the treatment of subluxations of the foot, or

(C) routine foot care (including the cutting or removal of corns or calluses, the trimming of nails, and other routine hygienic care);

(14) which are other than physicians' services (as defined in regulations promulgated specifically for purposes of this paragraph), services described by section 1395x(s)(2)(K) of this title, certified nurse-midwife services, qualified psychologist services, and services of a

certified registered nurse anesthetist, and which are furnished to an individual who is a patient of a hospital or critical access hospital by an entity other than the hospital or critical access hospital, unless the services are furnished under arrangements (as defined in section 1395x(w)(1) of this title) with the entity made by the hospital or critical access hospital;

(15)(A) which are for services of an assistant at surgery in a cataract operation (including subsequent insertion of an intraocular lens) unless, before the surgery is performed, the appropriate utilization and quality control peer review organization (under part B of subchapter XI of this chapter) or a carrier under section 1395u of this title has approved of the use of such an assistant in the surgical procedure based on the existence of a complicating medical condition, or

(B) which are for services of an assistant at surgery to which section 1395w-4(i)(2)(B) of this title applies;

(16) in the case in which funds may not be used for such items and services under the Assisted Suicide Funding Restriction Act of 1997 [42 U.S.C. 14401 et seq.];

(17) where the expenses are for an item or service furnished in a competitive acquisition area (as established by the Secretary under section 1395w-3(a) of this title) by an entity other than an entity with which the Secretary has entered into a contract under section 1395w-3(b) of this title for the furnishing of such an item or service in that area, unless the Secretary finds that the expenses were incurred in a case of urgent need, or in other circumstances specified by the Secretary;

(18) which are covered skilled nursing facility services described in section 1395yy(e)(2)(A)(i) of this title and which are furnished to an individual who is a resident of a skilled nursing facility or of a part of a facility that includes a skilled nursing facility (as determined under regulations), by an entity other than the skilled nursing facility, unless the services are furnished under arrangements (as defined in section 1395x(w)(1) of this title) with the entity made by the skilled nursing facility;

(19) which are for items or services which are furnished pursuant to a private contract described in section 1395a(b) of this title;

(20) in the case of outpatient occupational therapy services or outpatient physical therapy services furnished as an incident to a physician's professional services (as described in section 1395x(s)(2)(A) of this title), that do not meet the standards and conditions (other than any licensing requirement specified by the Secretary) under the second sentence of section 1395x(p) of this title (or under such sentence through the operation of section 1395x(g) of this title) as such standards and conditions would apply to such therapy services if furnished by a therapist; or

(21) where such expenses are for home health services (including medical supplies described in section 1395x(m)(5) of this title, but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who is under a plan of care of the home health agency if the claim for payment for such services is not submitted by the agency.

Paragraph (7) shall not apply to Federally qualified health center services described in section 1395x(aa)(3)(B) of this title.

PART 405--FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Subpart X—Rural Health Clinic and Federally Qualified Health Center Services

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 43 FR 8261, Mar. 1, 1978, unless otherwise noted.

§ 405.2400 Basis.

Subpart X is based on the provisions of the following sections of the Act: Section 1833 sets forth the amounts of payment for supplementary medical insurance services. Section 1861(aa) sets forth the rural health clinic services and Federally qualified health center services covered by the Medicare program.

[60 FR 63176, Dec. 8, 1995]

§ 405.2401 Scope and definitions.

(a) *Scope*. This subpart establishes the requirements for coverage and reimbursement of rural health clinic and Federally qualified health center services under Medicare.

(b) *Definitions*. As used in this subpart, unless the context indicates otherwise:

Act means the Social Security Act.

Allowable costs means costs that are incurred by a clinic or center and are reasonable in amount and proper and necessary for the efficient delivery of rural health clinic and Federally qualified health center services.

Beneficiary means an individual enrolled in the Supplementary Medical Insurance program for the Aged and Disabled (part of title XVIII of the Act).

Coinsurance means that portion of the clinic's charge for covered services for which the beneficiary is liable in addition to the deductible.

Carrier means an organization that has a contract with the Secretary to administer the benefits covered by this subpart.

Covered services means items or services for which the beneficiary is entitled to have payment made on his or her behalf under this subpart.

Deductible means:

(1) The first \$100 of expenses incurred by the beneficiary during any calendar year for items and services covered under Part B of title XVIII; and

(2) The expenses incurred for the first 3 pints of blood or 3 units of packed red blood cells furnished to a beneficiary during any calendar year. (See §§ 410.160 and 410.161 of this chapter for greater detail.)

Federally qualified health center (FQHC) means an entity that has entered into an agreement with CMS to meet Medicare program requirements under §§ 405.2434 and—

(1) Is receiving a grant under section 329, 330, or 340 of the Public Health Service Act, or is receiving funding from such a grant under a contract with the recipient of such a grant and meets the requirements to receive a grant under section 329, 330 or 340 of the Public Health Service Act;

(2) Based on the recommendation of the PHS, is determined by CMS to meet the requirements for receiving such a grant;

(3) Was treated by CMS, for purposes of part B, as a comprehensive federally funded health center (FFHC) as of January 1, 1990; or

(4) Is an outpatient health program or facility operated by a tribe or tribal organizations under the Indian Self Determination Act or by an Urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act.

CMS stands for Centers for Medicare & Medicaid Services.

Intermittent nursing care means a medically predictable need for nursing care from time to time, but usually not less frequently than once every 60 days.

Nurse-midwife means a registered professional nurse who meets the following requirements:

- (1) Is currently licensed to practice in the State as a registered professional nurse.
- (2) Is legally authorized under State law or regulations to practice as a nurse-midwife.
- (3) Except as provided in paragraph (b)(10)(iv) of this section, has completed a program of study and clinical experience for nurse-midwives, as specified by the State.
- (4) If the State does not specify a program of study and clinical experience that nurse-midwives must complete to practice in that State, meets one of the following conditions:
 - (i) Is currently certified as a nurse-midwife by the American College of Nurse-Midwives.
 - (ii) Has satisfactorily completed a formal education program (of at least one academic year) that, upon completion, qualifies the nurse to take the certification examination offered by the American College of Nurse-Midwives.
 - (iii) Has successfully completed a formal educational program for preparing registered nurses to furnish gynecological and obstetrical care to women during pregnancy, delivery, and the postpartum period, and care to normal newborns, and was practicing as a nurse-midwife for a total of 12 months during any 18-month period from August 8, 1976 to July 16, 1982.

Nurse practitioner and *physician assistant* means individuals who meet the applicable education, training experience and other requirements of § 491.2 of this chapter.

Part-time nursing care means nursing care that is required on less than a full-time basis,

that is, less than 8 hours a day or 40 hours a week.

Physician means the following:

- (1) A doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which the function is performed.
- (2) Within limitations as to the specific services furnished, a doctor of dentistry or dental or oral surgery, a doctor of optometry, a doctor of podiatry or surgical chiropody or a chiropractor. (See section 1861(r) of the Act for specific limitations.)
- (3) A resident (including residents as defined in § 415.152 of this chapter who meet the requirements in § 415.206(b) of this chapter for payment under the physician fee schedule).

Reporting period means a period of 12 consecutive months specified by the intermediary as the period for which a clinic or center must report its costs and utilization. The first and last reporting periods may be less than 12 months.

Rural health clinic means a facility that:

- (1) Has been determined by the Secretary to meet the requirements of section 1861(aa)(2) of the Act and part 491 of this chapter; and
- (2) Has filed an agreement with the Secretary in order to provide rural health clinic services under Medicare. (See § 405.2402.)

Secretary means the Secretary of Health and Human Services or his delegate.

Visiting nurse services means parttime or intermittent nursing care and related medical supplies (other than drugs or biologicals) furnished by a registered nurse or licensed practical nurse to a homebound patient. (Secs. 1102, 1833, 1861(aa), 1871, 1902(a)(13), Social Security Act; 49 Stat. 647, 79 Stat. 302, 322, and 331, 91 Stat. 1485 (42 U.S.C. 1302, 1395l, 1395hh, 1395x(aa), and 1396(a)(13)) [43 FR 8261,

Mar. 1, 1978, as amended at 43 FR 30526, July 14, 1978; 47 FR 21049, May 17, 1982; 47 FR 23448, May 28, 1982; 51 FR 41351, Nov. 14, 1986; 57 FR 24975, June 12, 1992; 59 FR 26958, May 25, 1994; 60 FR 63176, Dec. 8, 1995; 61 FR 14657, Apr. 3, 1996]

§ 405.2402 Basic requirements.

(a) *Certification by the State survey agency.* The rural health clinic must be certified in accordance with part 491 of this chapter.

(b) *Acceptance of the clinic as qualified to furnish rural health clinic services.* If the Secretary, after reviewing the survey agency recommendation and other evidence relating to the qualifications of the rural health clinic, determines that it meets the requirements of this subpart and of part 491 of this chapter, he will send the clinic:

- (1) Written notice of the determination; and
- (2) Two copies of the agreement to be filed as required by section 1861(aa)(1) of the Act.

(c) *Filing of agreement by the rural health clinic.* If the rural health clinic wishes to participate in the program, it must:

- (1) Have both copies of the agreement signed by an authorized representative; and
- (2) File them with the Secretary.

(d) *Acceptance by the Secretary.* If the Secretary accepts the agreement filed by the rural health clinic, he will return to the clinic one copy of the agreement, with a notice of acceptance specifying the effective date.

(e) *Duration of agreement.* The agreement shall be for a term of one year and may be renewed annually by mutual consent of the Secretary and the rural health clinic.

(f) *Appeal rights.* If the Secretary does not certify a rural health clinic, or refuses to enter into or renew an agreement, the facility is entitled to a hearing in accordance with part 498 of this chapter.

[43 FR 8261, Mar. 1, 1978, as amended at 52 FR 22454, June 12, 1987]

§ 405.2403 Content and terms of the agreement with the Secretary.

(a) Under the agreement, the rural health clinic agrees to the following:

(1) *Maintaining compliance with conditions.*

The clinic agrees to maintain compliance with the conditions set forth in part 491 of this chapter and to report promptly to CMS any failure to do so.

(2) *Charges to beneficiaries.* The clinic agrees not to charge the beneficiary or any other person for items and services for which the beneficiary is entitled to have payment made under the provisions of this part (or for which the beneficiary would have been entitled if the rural health clinic had filed a request for payment in accordance with § 410.165 of this chapter), except for any deductible or coinsurance amounts for which the beneficiary is liable under § 405.2410.

(3) *Refunds to beneficiaries.* (i) The clinic agrees to refund as promptly as possible any money incorrectly collected from beneficiaries or from someone on their behalf.

(ii) As used in this section, *money incorrectly collected* means sums collected in excess of the amount for which the beneficiary was liable under § 405.2410. It includes amounts collected at a time when the beneficiary was believed not to be entitled to Medicare benefits but:

- (A) The beneficiary is later determined to have been entitled to Medicare benefits; and
- (B) The beneficiary's entitlement period falls within the time the rural health clinic's agreement with the Secretary is in effect.

(4) *Beneficiary treatment.* (i) The clinic agrees to accept beneficiaries for care and treatment; and

(ii) The clinic agrees not to impose any limitations on the acceptance of beneficiaries for care and treatment that it does not impose on all other persons.

(b) *Additional provisions.* The agreement may contain any additional provisions that the Secretary finds necessary or desirable for

the efficient and effective administration of the Medicare program.

[43 FR 8261, Mar. 1, 1978, as amended at 51 FR 41351, Nov. 14, 1986]

§ 405.2404 Terminations of agreements.

(a) *Termination by rural health clinic.*

(1) *Notice to Secretary.* If the clinic wishes to terminate its agreement it shall file with the Secretary a written notice stating the intended effective date of termination.

(2) *Action by the Secretary.* (i) The Secretary may approve the date proposed by the clinic, or set a different date no later than 6 months after the date of the clinic's notice. (ii) The Secretary may approve a date which is less than 6 months after the date of notice if he determines that termination on that date would not:

(A) Unduly disrupt the furnishing of services to the community serviced by the clinic; or

(B) Otherwise interfere with the effective and efficient administration of the Medicare program.

(3) *Cessation of business.* If a clinic ceases to furnish services to the community, that shall be deemed to be a voluntary termination of the agreement by the clinic, effective on the last day of business.

(b) *Termination by the Secretary.* (1) *Cause for termination.* The Secretary may terminate an agreement if he determines that the rural health clinic:

(i) No longer meets the conditions for certification under part 491 of this chapter; or

(ii) Is not in substantial compliance with the provisions of the agreement, the requirements of this subpart, any other applicable regulations of this part, or any applicable provisions of title XVIII of the Act; or

(iii) Has undergone a change of ownership.

(2) *Notice of termination.* The Secretary will give notice of termination to the rural health

clinic at least 15 days before the effective date stated in the notice.

(3) *Appeal by the rural health clinic.* A rural health clinic may appeal the termination of its agreement in accordance with the provisions set forth in part 498 of this chapter.

(c) *Effect of termination.* Payment will not be available for rural health clinic services furnished on or after the effective date of termination.

(d) *Notice to the public.* Prompt notice of the date and effect of termination shall be given to the public, through publication in local newspapers:

(1) By the clinic, after the Secretary has approved or set a termination date; or

(2) By the Secretary, when he has terminated the agreement.

(e) *Conditions for reinstatement after termination of agreement by the Secretary.*

When an agreement with a rural health clinic is terminated by the Secretary, the rural health clinic may not file another agreement to participate in the Medicare program unless the Secretary:

(1) Finds that the reason for the termination of the prior agreement has been removed; and

(2) Is assured that the reason for the termination will not recur.

[43 FR 8261, Mar. 1, 1978, as amended at 52 FR 22454, June 12, 1987]

§ 405.2410 Application of Part B deductible and coinsurance.

(a) *Application of deductible.* (1) Medicare payment for rural health clinic services begins only after the beneficiary has incurred the deductible.

(2) Medicare payment for services covered under the Federally qualified health center benefit is not subject to the usual Part B deductible.

(b) *Application of coinsurance.* (1) The beneficiary is responsible for a coinsurance amount which cannot exceed 20 percent of

the clinic's reasonable customary charge for the covered service; and

(2)(i) The beneficiary's deductible and coinsurance liability, with respect to any one item or service furnished by the rural health clinic, may not exceed a reasonable amount customarily charged by the clinic for that particular item or service.

(ii) For any one item or service furnished by a Federally qualified health center, the coinsurance liability may not exceed 20 percent of a reasonable amount customarily charged by the center for that particular item or service.

[57 FR 24976, June 12, 1992]

§ 405.2411 Scope of benefits.

(a) Rural health clinic services reimbursable under this subpart are:

(1) The physicians' services specified in § 405.2412;

(2) Services and supplies furnished as an incident to a physician's professional service;

(3) The nurse practitioner or physician assistant services specified in § 405.2414;

(4) Services and supplies furnished as an incident to a nurse practitioner's or physician assistant's services; and

(5) Visiting nurse services.

(b) Rural health clinic services are reimbursable when furnished to a patient at the clinic, at a hospital or other medical facility, or at the patient's place of residence.

§ 405.2412 Physicians' services.

(a) Physicians' services are professional services that are performed by a physician at the clinic or are performed away from the clinic by a physician whose agreement with the clinic provides that he or she will be paid by the clinic for such services.

§ 405.2413 Services and supplies incident to a physician's services.

(a) Services and supplies incident to a physician's professional service are

reimbursable under this subpart if the service or supply is:

(1) Of a type commonly furnished in physicians' offices;

(2) Of a type commonly rendered either without charge or included in the rural health clinic's bill;

(3) Furnished as an incidental, although integral, part of a physician's professional services;

(4) Furnished under the direct, personal supervision of a physician; and

(5) In the case of a service, furnished by a member of the clinic's health care staff who is an employee of the clinic.

(b) Only drugs and biologicals which cannot be self-administered are included within the scope of this benefit.

§ 405.2414 Nurse practitioner and physician assistant services.

(a) Professional services are reimbursable under this subpart if:

(1) Furnished by a nurse practitioner, physician assistant, nurse midwife, or specialized nurse practitioner who is employed by, or receives compensation from, the rural health clinic;

(2) Furnished under the medical supervision of a physician;

(3) Furnished in accordance with any medical orders for the care and treatment of a patient prepared by a physician;

(4) They are of a type which the nurse practitioner, physician assistant, nurse midwife or specialized nurse practitioner who furnished the service is legally permitted to perform by the State in which the service is rendered; and

(5) They would be covered if furnished by a physician.

(b) The physician supervision requirement is met if the conditions specified in § 491.8(b) of this chapter and any pertinent requirements of State law are satisfied.

(c) The services of nurse practitioners, physician assistants, nurse midwives or

specialized nurse practitioners are not covered if State law or regulations require that the services be performed under a physician's order and no such order was prepared.

§ 405.2415 Services and supplies incident to nurse practitioner and physician assistant services.

(a) Services and supplies incident to a nurse practitioner's or physician assistant's services are reimbursable under this subpart if the service or supply is:

- (1) Of a type commonly furnished in physicians' offices;
 - (2) Of a type commonly rendered either without charge or included in the rural health clinic's bill;
 - (3) Furnished as an incidental, although integral part of professional services furnished by a nurse practitioner, physician assistant, nurse midwife, or specialized nurse practitioner;
 - (4) Furnished under the direct, personal supervision of a nurse practitioner, physician assistant, nurse midwife, specialized nurse practitioner or a physician; and
 - (5) In the case of a service, furnished by a member of the clinic's health care staff who is an employee of the clinic.
- (b) The direct personal supervision requirement is met in the case of a nurse practitioner, physician assistant, nurse midwife, or specialized nurse practitioner only if such a person is permitted to supervise such services under the written policies governing the rural health clinic.
- (c) Only drugs and biologicals which cannot be self-administered are included within the scope of this benefit.

§ 405.2416 Visiting nurse services.

(a) Visiting nurse services are covered if:

- (1) The rural health clinic is located in an area in which the Secretary has determined that there is a shortage of home health agencies;

(2) The services are rendered to a homebound individual;

(3) The services are furnished by a registered nurse, licensed practical nurse, or licensed vocational nurse who is employed by, or receives compensation for the services from the clinic; and

(4) The services are furnished under a written plan of treatment that is:

- (i) Established and reviewed at least every 60 days by a supervising physician of the rural health clinic or established by a nurse practitioner, physician assistant, nurse midwife, or specialized nurse practitioner and reviewed at least every 60 days by a supervising physician; and
- (ii) Signed by the nurse practitioner, physician assistant, nurse midwife, specialized nurse practitioner, or the supervising physician of the clinic.

(b) The nursing care covered by this section includes:

(1) Services that must be performed by a registered nurse, licensed practical nurse, or licensed vocational nurse if the safety of the patient is to be assured and the medically desired results achieved; and

(2) Personal care services, to the extent covered under Medicare as home health services. These services include helping the patient to bathe, to get in and out of bed, to exercise and to take medications.

(c) This benefit does not cover household and housekeeping services or other services that would constitute custodial care.

(d) For purposes of this section, *homebound* means an individual who is permanently or temporarily confined to his or her place of residence because of a medical or health condition. The individual may be considered homebound if he or she leaves the place of residence infrequently. For this purpose, "place of residence" does not include a hospital or long term care facility.

§ 405.2417 Visiting nurse services:

Determination of shortage of agencies.

A shortage of home health agencies exists if the Secretary determines that the rural health clinic:

(a) Is located in a county, parish, or similar geographic area in which there is no participating home health agency or adequate home health services are not available to patients of the rural health clinic;

(b) Has (or expects to have) patients whose permanent residences are not within the area serviced by a participating home health agency; or

(c) Has (or expects to have) patients whose permanent residences are not within a reasonable traveling distance, based on climate and terrain, of a participating home health agency.

PART 491--CERTIFICATION OF CERTAIN HEALTH FACILITIES

Subpart A—Rural Health Clinics: Conditions for Certification; and FQHCs Conditions for Coverage

§ 491.1 Purpose and scope.

This subpart sets forth the conditions that rural health clinics or FQHCs must meet in order to qualify for reimbursement under Medicare (title XVIII of the Social Security Act) and that rural health clinics must meet in order to qualify for reimbursement under Medicaid (title XIX of the Act).

[57 FR 24982, June 12, 1992]

§ 491.2 Definitions.

As used in this subpart, unless the context indicates otherwise:

Direct services means services provided by the clinic's staff.

FQHC means an entity as defined in § 405.2401(b).

Nurse practitioner means a registered professional nurse who is currently licensed to practice in the State, who meets the State's requirements governing the qualifications of nurse practitioners, and who meets one of the following conditions:

(1) Is currently certified as a primary care nurse practitioner by the American Nurses' Association or by the National Board of Pediatric Nurse Practitioners and Associates; or

(2) Has satisfactorily completed a formal 1 academic year educational program that:

(i) Prepares registered nurses to perform an expanded role in the delivery of primary care;

(ii) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and

(iii) Awards a degree, diploma, or certificate to persons who successfully complete the program; or

(3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements of paragraph (b)(2) of this section, and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding the effective date of this subpart.

Physician means a doctor of medicine or osteopathy legally authorized to practice medicine or surgery in the State.

Physician assistant means a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians, and who meets at least one of the following conditions:

(1) Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians; or

(2) Has satisfactorily completed a program for preparing physician's assistants that:

- (i) Was at least 1 academic year in length;
 - (ii) Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and
 - (iii) Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation; or
- (3) Has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements of paragraph (d)(2) of this section and assisted primary care physicians for a total of 12 months during the 18-month period that ended on December 31, 1986.

Rural area means an area that is not delineated as an urbanized area by the Bureau of the Census.

Rural health clinic or *clinic* means a clinic that is located in a rural area designated as a shortage area, is not a rehabilitation agency or a facility primarily for the care and treatment of mental diseases, and meets all other requirements of this subpart.

Shortage area means a defined geographic area designated by the Department as having either a shortage of personal health services (under section 1302(7) of the Public Health Service Act) or a shortage of primary medical care manpower (under section 332 of that Act).

Secretary means the Secretary of Health and Human Services, or any official to whom he has delegated the pertinent authority.

(Secs. 1102, 1833 and 1902(a)(13), Social Security Act: 49 Stat. 647, 91 Stat. 1485 (42 U.S.C. 1302, 1395l and 1396(a)(13))) [43 FR 5375, Feb. 8, 1978, as amended at 43 FR 30528, July 14, 1978. Redesignated at 50 FR 33034, Aug. 16, 1985, and further amended at 56 FR 8854, Mar. 1, 1991; 57 FR 24982, June 12, 1992]

§ 491.3 Certification procedures.

A rural health clinic will be certified for participation in Medicare in accordance with subpart S of 42 CFR part 405. The Secretary

will notify the State Medicaid agency whenever he has certified or denied certification under Medicare for a prospective rural health clinic in that State. A clinic certified under Medicare will be deemed to meet the standards for certification under Medicaid.

§ 491.4 Compliance with Federal, State and local laws.

The rural health clinic or FQHC and its staff are in compliance with applicable Federal, State and local laws and regulations.

(a) *Licensure of clinic or center.* The clinic or center is licensed pursuant to applicable State and local law.

(b) *Licensure, certification or registration of personnel.* Staff of the clinic or center are licensed, certified or registered in accordance with applicable State and local laws.

[57 FR 24982, June 12, 1992]

§ 491.5 Location of clinic.

(a) *Basic requirements.* (1) An RHC is located in a rural area that is designated as a shortage area.

(2) An FQHC is located in a rural or urban area that is designated as either a shortage area or an area that has a medically underserved population.

(3) Both the RHC and the FQHC may be permanent or mobile units.

(i) *Permanent unit.* The objects, equipment, and supplies necessary for the provision of the services furnished directly by the clinic or center are housed in a permanent structure.

(ii) *Mobile unit.* The objects, equipment, and supplies necessary for the provision of the services furnished directly by the clinic or center are housed in a mobile structure, which has fixed, scheduled location(s).

(iii) *Permanent unit in more than one location.* If clinic or center services are furnished at permanent units in more than one location, each unit is independently

considered for approval as a rural health clinic or for approval as an FQHC.

(b) *Exceptions.* (1) CMS does not disqualify an RHC approved under this subpart if the area in which it is located subsequently fails to meet the definition of a rural, shortage area.

(2) A private, nonprofit facility that meets all other conditions of this subpart except for location in a shortage area will be certified if, on July 1, 1977, it was operating in a rural area that is determined by the Secretary (on the basis of the ratio of primary care physicians to the general population) to have an insufficient supply of physicians to meet the needs of the area served.

(3) Determinations on these exceptions will be made by the Secretary upon application by the facility.

(c) *Criteria for designation of rural areas.*

(1) Rural areas are areas not delineated as urbanized areas in the last census conducted by the Census Bureau.

(2) Excluded from the rural area classification are:

(i) Central cities of 50,000 inhabitants or more;

(ii) Cities with at least 25,000 inhabitants which, together with contiguous areas having stipulated population density, have combined populations of 50,000 and constitute, for general economic and social purposes, single communities;

(iii) Closely settled territories surrounding cities and specifically designated by the Census Bureau as urban.

(3) Included in the rural area classification are those portions of extended cities that the Census Bureau has determined to be rural.

(d) *Criteria for designation of shortage areas.*

(1) The criteria for determination of shortage of personal health services (under section 1302(7) of the Public Health Services Act), are:

(i) The ratio of primary care physicians practicing within the area to the resident population;

(ii) The infant mortality rate;

(iii) The percent of the population 65 years of age or older; and

(iv) The percent of the population with a family income below the poverty level.

(2) The criteria for determination of shortage of primary medical care manpower (under section 332(a)(1)(A) of the Public Health Services Act) are:

(i) The area served is a rational area for the delivery of primary medical care services;

(ii) The ratio of primary care physicians practicing within the area to the resident population; and

(iii) The primary medical care manpower in contiguous areas is overutilized, excessively distant, or inaccessible to the population in this area.

(e) *Medically underserved population.*

A medically underserved population includes the following:

(1) A population of an urban or rural area that is designated by PHS as having a shortage of personal health services.

(2) A population group that is designated by PHS as having a shortage of personal health services.

(f) *Requirements specific to FQHCs.* An FQHC approved for participation in Medicare must meet one of the following criteria:

(1) Furnish services to a medically underserved population.

(2) Be located in a medically underserved area, as demonstrated by an application approved by PHS.

CROSS REFERENCE: See 42 CFR 110.203(g) (41 FR 45718, Oct. 15, 1976) and 42 CFR Part 5 (42 FR 1586, Jan. 10, 1978).

[43 FR 5375, Feb. 8, 1978. Redesignated at 50 FR 33034, Aug. 16, 1985, and amended

at 57 FR 24982, June 12, 1992; 61 FR 14658, Apr. 3, 1996]

§ 491.6 Physical plant and environment.

(a) *Construction.* The clinic or center is constructed, arranged, and maintained to insure access to and safety of patients, and provides adequate space for the provision of direct services.

(b) *Maintenance.* The clinic or center has a preventive maintenance program to ensure that:

(1) All essential mechanical, electrical and patient-care equipment is maintained in safe operating condition;

(2) Drugs and biologicals are appropriately stored; and

(3) The premises are clean and orderly.

(c) *Emergency procedures.* The clinic or center assures the safety of patients in case of non-medical emergencies by:

(1) Training staff in handling emergencies;

(2) Placing exit signs in appropriate locations; and

(3) Taking other appropriate measures that are consistent with the particular conditions of the area in which the clinic or center is located.

[57 FR 24983, June 12, 1992]

§ 491.7 Organizational structure.

(a) *Basic requirements.* (1) The clinic or center is under the medical direction of a physician, and has a health care staff that meets the requirements of § 491.8.

(2) The organization's policies and its lines of authority and responsibilities are clearly set forth in writing.

(b) *Disclosure.* The clinic or center discloses the names and addresses of:

(1) Its owners, in accordance with section 1124 of the Social Security Act (42 U.S.C. 132 A-3);

(2) The person principally responsible for directing the operation of the clinic or center; and

(3) The person responsible for medical direction.

[57 FR 24983, June 12, 1992]

§ 491.8 Staffing and staff responsibilities.

(a) *Staffing.* (1) The clinic or center has a health care staff that includes one or more physicians. Rural health clinic staffs must also include one or more physician's assistants or nurse practitioners.

(2) The physician member of the staff may be the owner of the rural health clinic, an employee of the clinic or center or under agreement with the clinic or center to carry out the responsibilities required under this section.

(3) The physician assistant, nurse practitioner, nurse-midwife, **clinical social worker**, or clinical psychologist member of the staff may be the owner or an employee of the clinic or center, or may furnish services under contract to the center.

(4) The staff may also include ancillary personnel who are supervised by the professional staff.

(5) The staff is sufficient to provide the services essential to the operation of the clinic or center.

(6) A physician, nurse practitioner, physician assistant, nurse-midwife, **clinical social worker**, or clinical psychologist is available to furnish patient care services at all times the clinic or center operates. In addition, for rural health clinics, a nurse practitioner or a physician assistant is available to furnish patient care services at least 60 percent of the time the clinic operates.

(b) *Physician responsibilities.* (1) The physician:

(i) Except for services furnished by a clinical psychologist in an FQHC, which State law permits to be provided without physician supervision, provides medical direction for the clinic's or center's health care activities and consultation for, and medical supervision of, the health care staff.

(ii) In conjunction with the physician's assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the clinic's or center's written policies and the services provided to Federal program patients; and

(iii) Periodically reviews the clinic's or center's patient records, provides medical orders, and provides medical care services to the patients of the clinic or center.

(2) A physician is present for sufficient periods of time, at least once in every 2 week period (except in extraordinary circumstances), to provide the medical direction, medical care services, consultation and supervision described in paragraph (b)(1) of this section and is available through direct telecommunication for consultation, assistance with medical emergencies, or patient referral. The extraordinary circumstances are documented in the records of the clinic or center.

(c) *Physician assistant and nurse practitioner responsibilities.* (1) The physician assistant and the nurse practitioner members of the clinic's or center's staff:

(i) Participate in the development, execution and periodic review of the written policies governing the services the clinic or center furnishes;

(ii) Participate with a physician in a periodic review of the patients' health records.

(2) The physician assistant or nurse practitioner performs the following functions, to the extent they are not being performed by a physician:

(i) Provides services in accordance with the clinic's or center's policies;

(ii) Arranges for, or refers patients to, needed services that cannot be provided at the clinic or center; and

(iii) Assures that adequate patient health records are maintained and transferred as required when patients are referred.

[57 FR 24983, June 12, 1992, as amended at 61 FR 14658, Apr. 3, 1996]

§ 491.9 Provision of services.

(a) *Basic requirements.* (1) All services offered by the clinic or center are furnished in accordance with applicable Federal, State, and local laws; and

(2) The clinic or center is primarily engaged in providing outpatient health services and meets all other conditions of this subpart.

(3) The laboratory requirements in paragraph (c)(2) of this section apply to RHCs, but do not apply to FQHCs.

(b) *Patient care policies.* (1) The clinic's or center's health care services are furnished in accordance with appropriate written policies which are consistent with applicable State law.

(2) The policies are developed with the advice of a group of professional personnel that includes one or more physicians and one or more physician assistants or nurse practitioners. At least one member is not a member of the clinic or center staff.

(3) The policies include:

(i) A description of the services the clinic or center furnishes directly and those furnished through agreement or arrangement.

(ii) Guidelines for the medical management of health problems which include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the clinic or center.

(iii) Rules for the storage, handling, and administration of drugs and biologicals.

(4) These policies are reviewed at least annually by the group of professional personnel required under paragraph (b)(2) of this section and reviewed as necessary by the clinic or center.

(c) *Direct services—*(1) *General.* The clinic or center staff furnishes those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office

or at the entry point into the health care delivery system. These include medical history, physical examination, assessment of health status, and treatment for a variety of medical conditions.

(2) *Laboratory*. These requirements apply to RHCs but not to FQHCs. The RHC provides laboratory services in accordance with part 493 of this chapter, which implements the provisions of section 353 of the Public Health Service Act. The RHC provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including:

- (i) Chemical examinations of urine by stick or tablet method or both (including urine ketones);
- (ii) Hemoglobin or hematocrit;
- (iii) Blood glucose;
- (iv) Examination of stool specimens for occult blood;
- (v) Pregnancy tests; and
- (vi) Primary culturing for transmittal to a certified laboratory.

(3) *Emergency*. The clinic or center provides medical emergency procedures as a first response to common lifethreatening injuries and acute illness and has available the drugs and biologicals commonly used in life saving procedures, such as analgesics, anesthetics (local), antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids.

(d) *Services provided through agreements or arrangements*. (1) The clinic or center has agreements or arrangements with one or more providers or suppliers participating under Medicare or Medicaid to furnish other services to its patients, including:

- (i) Inpatient hospital care;
- (ii) Physician(s) services (whether furnished in the hospital, the office, the patient's home, a skilled nursing facility, or elsewhere); and

(iii) Additional and specialized diagnostic and laboratory services that are not available at the clinic or center.

(2) If the agreements are not in writing, there is evidence that patients referred by the clinic or center are being accepted and treated.

[57 FR 24983, June 12, 1992, as amended at 58 FR 63536, Dec. 2, 1993]

§ 491.10 Patient health records.

(a) *Records system*. (1) The clinic or center maintains a clinical record system in accordance with written policies and procedures.

(2) A designated member of the professional staff is responsible for maintaining the records and for insuring that they are completely and accurately documented, readily accessible, and systematically organized.

(3) For each patient receiving health care services, the clinic or center maintains a record that includes, as applicable:

- (i) Identification and social data, evidence of consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;
- (ii) Reports of physical examinations, diagnostic and laboratory test results, and consultative findings;
- (iii) All physician's orders, reports of treatments and medications, and other pertinent information necessary to monitor the patient's progress;
- (iv) Signatures of the physician or other health care professional.

(b) *Protection of record information*. (1) The clinic or center maintains the confidentiality of record information and provides safeguards against loss, destruction or unauthorized use.

(2) Written policies and procedures govern the use and removal of records from the

clinic or center and the conditions for release of information.

(3) The patient's written consent is required for release of information not authorized to be released without such consent.

(c) *Retention of records.* The records are retained for at least 6 years from date of last entry, and longer if required by State statute. (Secs. 1102, 1833 and 1902(a)(13), Social Security Act; 49 Stat. 647, 91 Stat. 1485 (42 U.S.C. 1302, 13951 and 1396a(a)(13))) [43 FR 30529, July 14, 1978. Redesignated at 50 FR 33034, Aug. 16, 1985, as amended at 57 FR 24984, June 12, 1992]

§ 491.11 Program evaluation.

(a) The clinic or center carries out, or arranges for, an annual evaluation of its total program.

(b) The evaluation includes review of:

- (1) The utilization of clinic or center services, including at least the number of patients served and the volume of services;
- (2) A representative sample of both active and closed clinical records; and
- (3) The clinic's or center's health care policies.

(c) The purpose of the evaluation is to determine whether:

- (1) The utilization of services was appropriate;
- (2) The established policies were followed; and
- (3) Any changes are needed.

(d) The clinic or center staff considers the findings of the evaluation and takes corrective action if necessary.

[57 FR 24984, June 12, 1992]

Medicare Benefit Policy Manual
**CHAPTER 13 - RURAL HEALTH CLINIC (RHC) AND FEDERALLY QUALIFIED HEALTH
CENTER (FQHC) SERVICES**

10 - Rural Health Clinics (RHCs) Defined

(Rev. 1, 10-01-03)

§1861(aa)(2) of the Act

The statutory requirements that RHCs must meet to qualify for the Medicare benefit are in [§1861\(aa\)\(2\)](#) of the Social Security Act (the Act.) Rural Health Clinics (RHCs) are clinics that are located in areas designated by the Bureau of the Census as rural and by the Secretary of Department of Health and Human Services (DHHS) or the State as medically underserved. RHCs have been eligible for participation in the Medicare program since March 1, 1978. Services rendered by approved RHCs to Medicare beneficiaries are covered under Medicare effective with the date of the clinic's approval for participation. See [§30](#) for a description of covered services

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30 - Rural Health Clinic and Federally Qualified Health Center Service Defined

(Rev. 1, 10-01-03)

A3-3192.2, A3-3643, RHC-400, RHC-500

Payments for covered RHC/FQHC services furnished to Medicare beneficiaries are made on the basis of an all-inclusive rate per covered visit (except for pneumococcal and influenza vaccines and their administration, which is paid at 100 percent of reasonable cost). The term "visit" is defined as a face-to-face encounter between the patient and a physician, physician assistant, nurse practitioner, certified nurse midwife, visiting nurse, clinical psychologist, or **clinical social worker** during which an RHC/FQHC service is rendered. Encounters with (1) more than one health professional; and (2) multiple encounters with the same health professional which take place on the same day and at a single location, constitute a single visit. An exception occurs in cases in which the patient, subsequent to the first encounter, suffers an illness or injury requiring additional diagnosis or treatment.

30.1 - RHC Services

(Rev. 1, 10-01-03)

A3-3191.1, B3-2260.1, RHC-401, RHC-400A, PM A03-021, PM A02-044

RHC services are the following services furnished by an RHC:

- Physicians' services, as described in [§50](#);
- Services and supplies incident to a physician's services, as described in [§60](#);
- Services of nurse practitioners (NP), physician assistants (PA) (including certified nurse midwives (CNM)), as described in [§70](#);
- Services and supplies incident to the services of nurse practitioners and physician assistants (including services furnished by nurse midwives), as described in [§80](#);
- Visiting nurse (VN) services to the homebound, as described in [§90](#);
- Clinical psychologist (CP) and **clinical social worker services (CSW)**, as described in [§100](#) and [§110](#);

- Services and supplies incident to the services of clinical psychologists and **clinical social workers**, as described in §100 and §110;
- Services of registered dietitians or nutritional professionals for diabetes training services and medical nutrition therapy; and
- Otherwise covered drugs that are furnished by, and incident to, services of physicians and nonphysician practitioners of the RHC/FQHC.

The Medicare program makes payment directly to the RHCs for covered services furnished to Medicare beneficiaries. RHC services are covered when furnished to a patient at the clinic or center, the patient's place of residence, or elsewhere (e.g., the scene of an accident).

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110 - Clinical Social Worker (CSW) Services Away and at the RHC/FQHC Clinic or Center

(Rev. 1, 10-01-03)

RHC-419.2

(Rev. 1, 10-01-03)

RHC/FQHC services include the services provided by a clinical social worker.

110.1 - Clinical Social Worker Defined

(Rev. 1, 10-01-03)

RHC-419.2.A

- A **clinical social worker** is an individual who:
 - Possesses a master's or doctor's degree in social work;
 - Has performed at least two years of supervised clinical social work; and
 - Either:
 - Is licensed or certified as a clinical social worker by the State in which the services are performed; or
 - In the case of an individual in a State that does not provide for licensure or certification, has completed at least two years or 3,000 hours of post master's degree supervised clinical social work practice under the supervision of a master's level social worker in an appropriate setting such as a hospital, SNF, or clinic

110.2 - Clinical Social Worker Services Defined

(Rev. 1, 10-01-03)

RHC-419.2.B

Clinical social worker services for the diagnosis and treatment of mental illnesses and services and supplies furnished incident to such services are covered as long as the CSW is legally authorized to perform them under State law (or the State regulatory mechanism provided by State law) of the State in which such services are performed. The services that are covered are those that are otherwise covered if furnished by a physician or as an incident to a physician's professional service. Services furnished to an inpatient or outpatient that a hospital is required to provide as a requirement for participation are not included.

110.3 - Covered CSW Services

(Rev. 1, 10-01-03)

RHC-419.2.C

Clinical social worker services and supplies furnished incident to such services are covered as the services furnished by a physician or as incident to physician's services are covered. (See §60.) Coverage is limited to the services a CSW is legally authorized to perform in accordance with State law, including services and supplies furnished incident to such services and are those that are otherwise covered if furnished by a physician or incident to a physician's professional service. The services of a CSW may be covered in an RHC/FQHC if they are:

- The type of services that are otherwise covered if furnished by a physician, or incident to a physician's service;
- Performed by a person who meets the above definition of a CSW; and
- Not otherwise excluded from coverage.

State law or regulatory mechanism governing a CSW's scope of practice in the service area must be considered. Development of a list of services within the scope of practice is encouraged.

110.4 - Noncovered CSW Services

(Rev. 1, 10-01-03)

CSW services are not covered if they are otherwise excluded from Medicare coverage even though a CSW is authorized by State law to perform them. For example, the Medicare law excludes from coverage services that are not "reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member."

110.5 - Outpatient Mental Health Services Limitation

(Rev. 1, 10-01-03)

All covered therapeutic services furnished by qualified CSWs are subject to the outpatient psychiatric services limitation (i.e., only 62 1/2 percent of expenses for these services are considered incurred expenses for Medicare purposes). The limitation does not apply to diagnostic services.

110.6 - Services at the Clinic or Center

(Rev. 1, 10-01-03)

RHC-419.2.F

The services of clinical social workers performed at the clinic or center are RHC or FQHC services and are payable only to the clinic or center.

110.7 - Services Away From the Clinic or Center

(Rev. 1, 10-0111-03)

RHC-419.2.G

Clinical social workers who are employees of an RHC or FQHC, or who are compensated by the clinic or center for providing services furnished to clinic or center patients in a location other than at the clinic/center facility, may furnish services to clinic/center patients at the clinic/center facility or in other locations, such as in a patient's home. These services are RHC/FQHC services and are reimbursable only to the clinic or center.

A clinical social worker that is compensated by the clinic/center for services in locations other than the clinic/center, may not bill the Medicare program through the carrier for services furnished to Medicare beneficiaries who are clinic/center patients, regardless of place of service.

Rural Health Clinic and Federally Qualified Health Center Manual

CHAPTER IV- COVERAGE AND EXCLUSIONS

400. RURAL HEALTH CLINIC (RHC) AND FEDERALLY QUALIFIED HEALTH center (FQHC) SERVICES DEFINED

A. RHC services are the following services furnished by an RHC:

- o Physicians' services, as described in §405;
- o Services and supplies incident to a physician's services, as described in §406;
- o Services of nurse practitioners, physician assistants (including clinical nurse midwives), as described in §408;
- o Services and supplies incident to the services of nurse practitioners and physician assistants (including services furnished by nurse midwives), as described in §410;
- o Visiting nurse services to the homebound, as described in §412;
- o Clinical psychologist and clinical social worker services, as described in §419; and
- o Services and supplies incident to the services of clinical psychologists and clinical social workers, as described in §419.

...

419.2 Clinical Social Worker (CSW) Services.--RHC/FQHC services include the services provided by a clinical social worker.

A. Clinical Social Worker Defined.--A clinical social worker is an individual who:

- o Possesses a master's or doctor's degree in social work;
- o Has performed at least 2 years of supervised clinical social work; and
- o Either
 - Is licensed or certified as a clinical social worker by the State in which the services are performed; or
 - In the case of an individual in a State that does not provide for licensure or certification, has completed at least 2 years or 3,000 hours of post master's degree supervised clinical social work practice under the supervision of a master's level social worker in an appropriate setting such as a hospital, SNF, or clinic.

B. Clinical Social Worker Services Defined.-- Covered services are services that the CSW is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are performed for the diagnosis and treatment of mental illnesses. Services furnished to an inpatient of a hospital or an inpatient of a SNF that the SNF is required to provide as a requirement for participation are not included. The services that are covered are those that are otherwise covered if furnished by a physician or as an incident to a physician's professional service.

C. Covered CSW Services.--Coverage is limited to the services a CSW is legally authorized to perform in accordance with State law (or State regulatory mechanism established by State law). The services of a CSW may be covered in an RHC/FQHC if they are:

- o The type of services that are otherwise covered if furnished by a physician, or incident to a physician's service;
- o Performed by a person who meets the above definition of a CSW; and
- o Not otherwise excluded from coverage.

State law or regulatory mechanism governing a CSW's scope of practice in the service area must be considered. Development of a list of services within the scope of practice is encouraged.

D. Noncovered Services.--Services of a CSW are not covered when furnished to inpatients of a hospital or to inpatients of a SNF if the services furnished in the SNF are those that the SNF is required to furnish as a condition of participation in Medicare. In addition, CSW services are not covered if they are otherwise excluded from Medicare coverage even though a CSW is authorized by State law to perform them. For example, the Medicare law excludes from coverage services that are not "reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member."

E. Outpatient Mental Health Services Limitation.--All covered therapeutic services furnished by qualified CSWs are subject to the outpatient psychiatric services limitation in §613 (i.e., only 62 1/2 percent of expenses for these services are considered incurred expenses for Medicare purposes). The limitation does not apply to diagnostic services.

F. Services at the Clinic or center.--The services of a clinical social workers performed at the clinic or center are RHC or FQHC services and are payable only to the clinic or center.

G. Services Away From the Clinic or center.--Clinical social workers who are employees of an RHC or FQHC, or who are compensated by the clinic or center for providing services furnished to clinic or center patients in a location other than at the clinic/center facility, may furnish services to clinic/center patients at the clinic/center facility or in other locations, such as in a patient's home. These services are RHC/FQHC services and are reimbursable only to the clinic or center.

A clinical social worker who is an employee of an RHC or FQHC, or who is compensated by the clinic/center for services in locations other than the clinic/center, may not bill the Medicare program through the carrier for services furnished to Medicare beneficiaries who are clinic/center patients, regardless of place of service.

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612. MENTAL HEALTH SERVICES LIMITATION-EXPENSES INCURRED FOR PHYSICIANS', CLINICAL PSYCHOLOGISTS' AND CLINICAL SOCIAL WORKERS' SERVICES RENDERED IN A RURAL HEALTH CLINIC OR FEDERALLY QUALIFIED HEALTH center

Regardless of the actual expenses for physicians', clinical psychologists' and/or clinical social workers', services incurred in connection with the treatment of mental, psychoneurotic or personality disorders of persons who are not inpatients of hospitals, the amount of such expenses that may be counted in a calendar year is the lesser of 62.5 percent of expenses or the amount shown in the following table:

<u>Year</u>	<u>Recognized Limit</u>	<u>Payment Limit</u>
Through 12/31/87	\$ 312.50	\$ 250.00
1/1/88 - 12/31/88	\$ 562.50	\$ 450.00
1/1/89 - 12/31/89	\$ 1,375.00	\$ 1,100.00
12/31/89 and later	No Limit	No Limit

These limits apply to revenue code 910.

After 1989, there is no dollar limit.

Mental, psychoneurotic, and personality disorders are defined as the specific psychiatric conditions described in the American Psychiatric Association's Diagnostic and Statistical Manual-Mental Disorders. The limitation applies to expenses incurred in connection with one of these psychiatric conditions. It is applicable to physicians' services or items and supplies furnished by physicians. No distinction is made when applying the limitation between the services of psychiatrists and nonpsychiatric physicians. Therapeutic services furnished by other health practitioners are subject to the mental health treatment limitation when rendered in connection with a condition included in the definition of "mental, psychoneurotic, and personality disorders".

Charges for initial diagnostic services (i.e., psychiatric testing and evaluation used to diagnose the patient's illness) are not subject to this limitation. The limitation is applied only to therapeutic services. Apply the outpatient mental health limitation to the physician's or other mental health professional's therapeutic services, but not to his/her diagnostic services (except those administered to follow the progress of a course of psychiatric *treatment for a diagnosed condition*). *Bill therapeutic services under revenue code 910.*

An initial psychiatric visit to a physician for his personal professional services often combines diagnostic evaluation and the start of therapy; such a visit is neither solely diagnostic nor solely therapeutic. Therefore, the reasonable course is to deem the initial visit to be diagnostic so that the limitation does not apply. Separating diagnostic and therapeutic components of a visit is not administratively feasible, and determining the entire visit to be therapeutic is not justifiable since some diagnostic work must be done before even a tentative diagnosis can be made, and certainly before therapy can be instituted. Moreover, the patient must not be disadvantaged because therapeutic as well as diagnostic services were provided in the initial visit. Similarly, in the cases where a physician's diagnostic psychiatric services take more than one visit, the limitation is not applied to the additional visits. However, it is expected such cases are few. Therefore, when you bill for more than one visit for diagnostic services, document the case to show the reason for more than one diagnostic visit.

Thus, the following types of diagnostic services would be exempt from the limitation:

- o Psychiatric testing - this refers to use of actual testing instruments such as intelligence tests;
- o Psychiatric consultations - evaluation made by a physician or non-physician for purposes of preparing a report for the attending physician; or
- o Initial psychiatric visits - evaluation made by a physician who will test the patient.

FEDERALLY QUALIFIED HEALTH CENTERS – CLINICAL SOCIAL WORK SERVICES/CLINICAL SOCIAL WORKERS

The Omnibus Reconciliation Act of 1990 (OBRA '90) amended Section 1861(s)(E) of the Social Security Act to include Federally Qualified Health Centers (FQHCs) effective October 1, 1991.

The significance of this change is that Medicare FQHC services are defined in relation to rural health clinic "core services," which include services provided by physicians, physician assistants, nurse practitioners, nurse midwives, clinical psychologists, clinical social workers, and services and supplies incident to such services. In addition, Medicare FQHC services are also defined to include "preventive primary health services."

Section 4161(a)(4) of OBRA '90 defines a FQHC as an entity that

- Is a grantee under sections 329, 330, or 340 of the Public Health Service Act, which are commonly known as Community Health Centers, Migrant Health Centers, and Health Care for the Homeless Programs
- Is a recipient of funds from a grantee of sections 329, 330, or 340 pursuant to a contract with that grantee, and meets the requirements to receive a grant directly under sections 329, 330, or 340
- Is determined by the U.S. Department of Health and Human Services, on the basis of a recommendation by the Health Resources and Services Administration in the Public Health Service (PHS) to meet the requirements for receiving a grant under sections 329, 330, or 340.

In accordance with the provisions of OBRA '90, Medicare FQHC reimbursement is based on the same cost-based reimbursement principles that apply to rural health clinics. The OBRA '90 amendment (Section 4161(a)(3)) provides for first dollar coverage for Medicare beneficiaries in FQHCs. Specifically, beneficiaries do not have to pay any deductibles for expenses incurred for FQHC services, and an FQHC can waive full or partial collection of coinsurance from a patient based on the sliding scale requirement of the Public Health Service.¹²

These provisions were codified in the Medicare statute (Title XVIII of the Social Security Act) at (1) section 1861(aa), which defines FQHC services as being those of physicians, nurse practitioners, physician's assistants, clinical social workers, and clinical psychologists, and services incident to the services of those providers and section 1833, which stipulates cost-based reimbursement for all FQHC services. FQHCs are subject to the 62.5 percent payment restriction for any visit for which a mental health condition is the primary diagnosis. (personal communication with D. Hawkins, vice president for Federal, State, and Public Affairs, National Association of Community Health Centers, Washington, DC, May, 25, 2005).

It is important to note that FQHCs are also covered under Medicaid for the same rural health clinic core services provided for under Medicare. Although this is certainly a benefit for many FQHCs,

¹² National Association of Community Health Centers (NACHAC), Inc. (1990, December). *Federally qualified health centers: Services of clinical psychologists and clinical social workers under FQHC and RHC*. Issue brief. Washington, DC: NACHAC.

because they typically serve both Medicare and Medicaid beneficiaries, unfortunately the different statutory provisions will contribute to confusing administrative procedures. Nonetheless, covering FQHCs for rural health clinic core services means extending the settings in which clinical social workers can be reimbursed, and increases the opportunity for underserved populations to receive mental health services.

The Medicaid FQHC statutory amendment predates that of Medicare. Section 6404 of OBRA '89 amended Section 1905(a)(2) of the Social Security Act to provide for coverage of FQHCs and other ambulatory services offered by an FQHC under Medicaid, effective April 1, 1990. It was the 1989 law that created a mandatory service called Federally Qualified Health Center services that could only be provided by FQHCs. OBRA '89 amended sections 329, 330, or 340 PHS grantees or centers that could qualify as Section 329, 330, or 240 grantees ("look-alikes").

OBRA '89 provided that FQHCs were entitled to be reimbursed 100 percent of reasonable cost for services provided for Medicaid beneficiaries as long as the services meet the definition of rural health clinic services as provided in Medicare law or are one of the ambulatory services provided in the state Medicaid program. The CMS instructions to states allow for the use of different payment systems as long as the principle of reimbursement based on 100 percent of the costs that are reasonable and related to the cost of providing the FQHC services is maintained.

States are required to reimburse approved FQHCs for the rural health clinic core services even if they are not included in the Medicaid state plan, although such state plans must be amended to meet the requirements of the new law. Other ambulatory services provided by an FQHC, however, can only be considered a covered FQHC service if it is in a state's Medicaid plan.

All section 329, 330, or 340 federally funded health centers are automatically designated FQHCs. The look-alikes are subject to approval by the (HCFA) based on recommendations from the Health Resources and Services Administration in the Public Health Service. Such facilities may qualify for a waiver of up to two years to fully comply with the requirements of the section 329, 330, or 340 federally funded health centers.

SOCIAL SECURITY ACT § 1902

42USC1396a

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XIX--GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

Sec. 1396a. State plans for medical assistance

(a) Contents

A State plan for medical assistance must--

(1) provide that it shall be in effect in all political subdivisions of the State, and, if administered by them, be mandatory upon them;

(2) provide for financial participation by the State equal to not less than 40 per centum of the non-Federal share of the expenditures under the plan with respect to which payments under section 1396b of this title are authorized by this subchapter; and, effective July 1, 1969, provide for financial participation by the State equal to all of such non-Federal share or provide for distribution of funds from Federal or State sources, for carrying out the State plan, on an equalization or other basis which will assure that the lack of adequate funds from local sources will not result in lowering the amount, duration, scope, or quality of care and services available under the plan;

(3) provide for granting an opportunity for a fair hearing before the State agency to any individual whose claim for medical assistance under the plan is denied or is not acted upon with reasonable promptness;

.....

(13) provide--

(A) for a public process for determination of rates of payment under the plan for hospital services, nursing facility services, and services of intermediate care facilities for the mentally retarded under which--

(i) proposed rates, the methodologies underlying the establishment of such rates, and justifications for the proposed rates are published,

(ii) providers, beneficiaries and their representatives, and other concerned State residents are given a reasonable opportunity for review and comment on the proposed rates, methodologies, and justifications,

(iii) final rates, the methodologies underlying the establishment of such rates, and justifications for such final rates are published, and

(iv) in the case of hospitals, such rates take into account (in a manner consistent with section 396r-4 of this title) the situation of hospitals which serve a disproportionate number of low-income patients with special needs;

(B) for payment for hospice care in amounts no lower than the amounts, using the same methodology, used under part A of subchapter XVIII of this chapter and for payment of amounts under section 1396d(o)(3) of this title; except that in the case of hospice care which is furnished to an individual who is a resident of a nursing facility or intermediate care facility for the mentally retarded, and who would be eligible under the plan for nursing facility services or services in an intermediate care facility for the mentally retarded if he had not elected to receive hospice care, there shall be paid an additional amount, to take into account the room and board furnished by the facility, equal to at least 95 percent of the rate that would have been paid by the State under the plan for facility services in that facility for that individual; and

(C)(i) for payment for services described in clause (B) or (C) of section 1396d(a)(2) of this title under the plan of 100 percent (or 95 percent for services furnished during fiscal year 2000, fiscal year 2001, or fiscal year 2002, 90 percent for services furnished during fiscal year 2003, or 85 percent for services furnished during fiscal year 2004) of costs which are reasonable and related to the cost of furnishing such services or based on such other tests of reasonableness, as the Secretary prescribes in regulations under section 1395l(a)(3) of this title, or, in the case of services to which those regulations do not apply, on the same methodology used under section 1395l(a)(3) of this title and (ii) in carrying out clause (i) in the case of services furnished by a Federally-qualified health center or a rural health clinic pursuant to a contract between the center and an organization under section 1396b(m) of this title, for payment to the center or clinic at least quarterly by the State of a supplemental payment equal to the amount (if any) by which the amount determined under clause (i) exceeds the amount of the payments provided under such contract;

(14) provide that enrollment fees, premiums, or similar charges, and deductions, cost sharing, or similar charges, may be imposed only as provided in section 1396o of this title;

(15) Repealed. Pub. L. 100-360, title III, Sec. 301(e)(2)(C), as added by Pub. L. 100-485, title VI, Sec. 608(d)(14)(I)(iii), Oct. 13, 1988, 102 Stat. 2416;

(16) provide for inclusion, to the extent required by regulations prescribed by the Secretary, of provisions (conforming to such regulations) with respect to the furnishing of medical assistance under the plan to individuals who are residents of the State but are absent therefrom;

.....,

SOCIAL SECURITY ACT § 1905

42USC1396d

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XIX--GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

Sec. 1396d. Definitions

For purposes of this subchapter--

(a) Medical assistance

The term "medical assistance" means payment of part or all of the cost of the following care and services (if provided in or after the third month before the month in which the recipient makes application for assistance or, in the case of medicare cost-sharing with respect to a qualified medicare beneficiary described in subsection (p)(1) of this section, if provided after the month in which the individual becomes such a beneficiary) for individuals, and, with respect to physicians' or dentists' services, at the option of the State, to individuals (other than individuals with respect to whom there is being paid, or who are eligible, or would be eligible if they were not in a medical institution, to have paid with respect to them a State supplementary payment and are eligible for medical assistance equal in amount, duration, and scope to the medical assistance made available to individuals described in section 1396a(a)(10)(A) of this title) not receiving aid or assistance under any plan of the State approved under subchapter I, X, XIV, or XVI of this chapter, or part A of subchapter IV of this chapter, and with respect to whom supplemental security income benefits are not being paid under subchapter XVI of this chapter, who are--

(i) under the age of 21, or, at the option of the State, under the age of 20, 19, or 18 as the State may choose,

(ii) relatives specified in section 606(b)(1) \1\ of this title with whom a child is living if such child is (or would, if needy, be) a dependent child under part A of subchapter IV of this chapter,

\1\ See References in Text note below.

(iii) 65 years of age or older,

(iv) blind, with respect to States eligible to participate in the State plan program established under subchapter XVI of this chapter,

(v) 18 years of age or older and permanently and totally disabled, with respect to States eligible to participate in the State plan program established under subchapter XVI of this chapter,

(vi) persons essential (as described in the second sentence of this subsection) to individuals receiving aid or assistance under State plans approved under subchapter I, X, XIV, or XVI of this chapter,

(vii) blind or disabled as defined in section 1382c of this title, with respect to States not eligible to participate in the State plan program established under subchapter XVI of this chapter,

(viii) pregnant women,

(ix) individuals provided extended benefits under section 1396r-6 of this title,

(x) individuals described in section 1396a(u)(1) of this title,

(xi) individuals described in section 1396a(z)(1) of this title, or

(xii) employed individuals with a medically improved disability (as defined in subsection (v) of this section), but whose income and resources are insufficient to meet all of such cost--

(1) inpatient hospital services (**other than services in an institution for mental diseases**);

(2)(A) outpatient hospital services, (B) consistent with State law permitting such services, rural health clinic services (as defined in subsection (l)(1) of this section) and any other ambulatory services which are offered by a rural health clinic (as defined in subsection (l)(1) of this section) and which are otherwise included in the plan, and (C) Federally-qualified health center services (as defined in subsection (l)(2) of this section) and any other ambulatory services offered by a Federally-qualified health center and which are otherwise included in the plan;

(3) other laboratory and X-ray services;

(4)(A) nursing facility services (other than services in an institution for mental diseases) for individuals 21 years of age or older; (B) early and periodic screening, diagnostic, and treatment services (as defined in subsection (r) of this section) for individuals who are eligible under the plan and are under the age of 21; and (C) family planning services and supplies furnished (directly or under arrangements with others) to individuals of child-bearing age (including minors who can be considered to be sexually active) who are eligible under the State plan and who desire such services and supplies;

(5)(A) physicians' services furnished by a physician (as defined in section 1395x(r)(1) of this title), whether furnished in the office, the patient's home, a hospital, or a nursing facility, or elsewhere, and (B) medical and surgical services furnished by a dentist (described in section 1395x(r)(2) of this title) to the extent such services may be performed under State law either by a doctor of medicine or by a doctor of dental surgery or dental medicine and would be described in clause (A) if furnished by a physician (as defined in section 1395x(r)(1) of this title);

(6) medical care, or any other type of remedial care recognized under State law, furnished by licensed practitioners within the scope of their practice as defined by State law;

(7) home health care services;

(8) private duty nursing services;

(9) clinic services furnished by or under the direction of a physician, without regard to whether the clinic itself is administered by a physician, including such services furnished outside the clinic by clinic personnel to an eligible individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address;

(10) dental services;

(11) physical therapy and related services;

(12) prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist, whichever the individual may select;

(13) other diagnostic, screening, preventive, and rehabilitative services, including any medical or remedial services (provided in a facility, a home, or other setting) recommended by a physician or other licensed practitioner of the healing arts within the scope of their practice under State law, for the maximum reduction of physical or mental disability and restoration of an individual to the best possible functional level;

(14) inpatient hospital services and nursing facility services for individuals 65 years of age or over in an institution for mental diseases;

(15) services in an intermediate care facility for the mentally retarded (other than in an institution for mental diseases) for individuals who are determined, in accordance with section 1396a(a)(31) of this title, to be in need of such care;

(16) effective January 1, 1973, inpatient psychiatric hospital services for individuals under age 21, as defined in subsection (h) of this section;

(17) services furnished by a nurse-midwife (as defined in section 1395x(gg) of this title) which the nurse-midwife is legally authorized to perform under State law (or the State regulatory

mechanism provided by State law), whether or not the nurse-midwife is under the supervision of, or associated with, a physician or other health care provider, and without regard to whether or not the services are performed in the area of management of the care of mothers and babies throughout the maternity cycle;

(18) hospice care (as defined in subsection (o) of this section);

(19) **case management services** (as defined in section 1396n(g)(2) of this title) and TB-related services described in section 1396a(z)(2)(F) of this title;

(20) respiratory care services (as defined in section 1396a(e)(9)(C) of this title);

(21) services furnished by a certified pediatric nurse practitioner or certified family nurse practitioner (as defined by the Secretary) which the certified pediatric nurse practitioner or certified family nurse practitioner is legally authorized to perform under State law (or the State regulatory mechanism provided by State law), whether or not the certified pediatric nurse practitioner or certified family nurse practitioner is under the supervision of, or associated with, a physician or other health care provider;

(22) home and community care (to the extent allowed and as defined in section 1396t of this title) for functionally disabled elderly individuals;

(23) community supported living arrangements services (to the extent allowed and as defined in section 1396u of this title);

(24) personal care services furnished to an individual who is not an inpatient or resident of a hospital, nursing facility, intermediate care facility for the mentally retarded, or institution for mental disease that are (A) authorized for the individual by a physician in accordance with a plan of treatment or (at the option of the State) otherwise authorized for the individual in accordance with a service plan approved by the State, (B) provided by an individual who is qualified to provide such services and who is not a member of the individual's family, and (C) furnished in a home or other location;

(25) primary care case management services (as defined in subsection (t) of this section);

(26) services furnished under a PACE program under section 1396u-4 of this title to PACE program eligible individuals enrolled under the program under such section; and

(27) any other medical care, and any other type of remedial care recognized under State law, specified by the Secretary,

except as otherwise provided in paragraph (16), such term does not include--

(A) any such payments with respect to care or services for any individual who is an inmate of a public institution (except as a patient in a medical institution); or

(B) any such payments with respect to care or services for any individual who has not attained 65 years of age and who is a patient in an institution for mental diseases.

For purposes of clause (vi) of the preceding sentence, a person shall be considered essential to another individual if such person is the spouse of and is living with such individual, the needs of such person are taken into account in determining the amount of aid or assistance furnished to such individual (under a State plan approved under subchapter I, X, XIV, or XVI of this chapter), and such person is determined, under such a State plan, to be essential to the well-being of such individual. The payment described in the first sentence may include expenditures for medicare cost-sharing and for premiums under part B of subchapter XVIII of this chapter for individuals who are eligible for medical assistance under the plan and (A) are receiving aid or assistance under any plan of the State approved under subchapter I, X, XIV, or XVI of this chapter, or part A of subchapter IV of this

chapter, or with respect to whom supplemental security income benefits are being paid under subchapter XVI of this chapter, or (B) with respect to whom there is being paid a State supplementary payment and are eligible for medical assistance equal in amount, duration, and scope to the medical assistance made available to individuals described in section 1396a(a)(10)(A) of this title, and, except in the case of individuals 65 years of age or older and disabled individuals entitled to health insurance benefits under subchapter XVIII of this chapter who are not enrolled under part B of subchapter XVIII of this chapter, other insurance premiums for medical or any other type of remedial care or the cost thereof. No service (including counseling) shall be excluded from the definition of "medical assistance" solely because it is provided as a treatment service for alcoholism or drug dependency.

...

(h) Inpatient psychiatric hospital services for individuals under age 21

(1) For purposes of paragraph (16) of subsection (a) of this section, the term "inpatient psychiatric hospital services for individuals under age 21" includes only--

(A) inpatient services which are provided in an institution (or distinct part thereof) which is a psychiatric hospital as defined in section 1395x(f) of this title or in another inpatient setting that the Secretary has specified in regulations;

(B) inpatient services which, in the case of any individual (i) involve active treatment which meets such standards as may be prescribed in regulations by the Secretary, and (ii) a team, consisting of physicians and other personnel qualified to make determinations with respect to mental health conditions and the treatment thereof, has determined are necessary on an inpatient basis and can reasonably be expected to improve the condition, by reason of which such services are necessary, to the extent that eventually such services will no longer be necessary; and

(C) inpatient services which, in the case of any individual, are provided prior to (i) the date such individual attains age 21, or (ii) in the case of an individual who was receiving such services in the period immediately preceding the date on which he attained age 21, (I) the date such individual no longer requires such services, or (II) if earlier, the date such individual attains age 22;

(2) Such term does not include services provided during any calendar quarter under the State plan of any State if the total amount of the funds expended, during such quarter, by the State (and the political subdivisions thereof) from non-Federal funds for inpatient services included under paragraph (1), and for active psychiatric care and treatment provided on an outpatient basis for eligible mentally ill children, is less than the average quarterly amount of the funds expended, during the 4-quarter period ending December 31, 1971, by the State (and the political subdivisions thereof) from non-Federal funds for such services.

(i) Institution for mental diseases

The term "institution for mental diseases" means a hospital, nursing facility, or other institution of more than 16 beds, that is primarily engaged in providing diagnosis, treatment, or care of persons with mental diseases, including medical attention, nursing care, and related services.

...

(l) Rural health clinics

(1) The terms ``rural health clinic services" and ``rural health clinic" have the meanings given such terms in section 1395x(aa) of this title, except that (A) clause (ii) of section 1395x(aa)(2) of this title shall not apply to such terms, and (B) the physician arrangement required under section 1395x(aa)(2)(B) of this title shall only apply with respect to rural health clinic services and, with respect to other ambulatory care services, the physician arrangement required shall be only such as may be required under the State plan for those services.

(2)(A) The term ``Federally-qualified health center services" means services of the type described in subparagraphs (A) through (C) of section 1395x(aa)(1) of this title when furnished to an individual as an \2\ patient of a Federally-qualified health center and, for this purpose, any reference to a rural health clinic or a physician described in section 1395x(aa)(2)(B) of this title is deemed a reference to a Federally-qualified health center or a physician at the center, respectively.

\2\ So in original. Probably should be ``a".

(B) The term ``Federally-qualified health center" means an entity which--

(i) is receiving a grant under section 254b of this title,

(ii) (l) is receiving funding from such a grant under a contract with the recipient of such a grant, and

(ll) meets the requirements to receive a grant under section 254b of this title,

(iii) based on the recommendation of the Health Resources and Services Administration within the Public Health Service, is determined by the Secretary to meet the requirements for receiving such a grant, including requirements of the Secretary that an entity may not be owned, controlled, or operated by another entity, or

(iv) was treated by the Secretary, for purposes of part B of subchapter XVIII of this chapter, as a comprehensive Federally funded health center as of January 1, 1990;

and includes an outpatient health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act (Public Law 93-638) [25 U.S.C. 450f et seq.] or by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act [25 U.S.C. 1651 et seq.] for the provision of primary health services. In applying clause (ii), \3\ the Secretary may waive any requirement referred to in such clause for up to 2 years for good cause shown.

\3\ So in original. Probably should be clause ``(iii)". See References in Text note below.

...

(o) Optional hospice benefits

(1)(A) Subject to subparagraph (B), the term ``hospice care" means the care described in section 1395x(dd)(1) of this title furnished by a hospice program (as defined in section 1395x(dd)(2) of this title) to a terminally ill individual who has voluntarily elected (in accordance with paragraph (2)) to have payment made for hospice care instead of having payment made for certain benefits described in section 1395d(d)(2)(A) of this title and for which payment may otherwise be

made under subchapter XVIII of this chapter and intermediate care facility services under the plan. For purposes of such election, hospice care may be provided to an individual while such individual is a resident of a skilled nursing facility or intermediate care facility, but the only payment made under the State plan shall be for the hospice care.

(B) For purposes of this subchapter, with respect to the definition of hospice program under section 1395x(dd)(2) of this title, the Secretary may allow an agency or organization to make the assurance under subparagraph (A)(iii) of such section without taking into account any individual who is afflicted with acquired immune deficiency syndrome (AIDS).

(2) An individual's voluntary election under this subsection--

(A) shall be made in accordance with procedures that are established by the State and that are consistent with the procedures established under section 1395d(d)(2) of this title;

(B) shall be for such a period or periods (which need not be the same periods described in - section 1395d(d)(1) of this title) as the State may establish; and

(C) may be revoked at any time without a showing of cause and may be modified so as to - change the hospice program with respect to which a previous election was made.

(3) In the case of an individual--

(A) who is residing in a nursing facility or intermediate care facility for the mentally retarded and is receiving medical assistance for services in such facility under the plan,

(B) who is entitled to benefits under part A of subchapter XVIII of this chapter and has elected, under section 1395d(d) of this title, to receive hospice care under such part, and

(C) with respect to whom the hospice program under such subchapter and the nursing facility or intermediate care facility for the mentally retarded have entered into a written agreement under which the program takes full responsibility for the professional management of the individual's hospice care and the facility agrees to provide room and board to the individual,

instead of any payment otherwise made under the plan with respect to the facility's services, the State shall provide for payment to the hospice program of an amount equal to the additional amount determined in section 1396a(a)(13)(B) of this title and, if the individual is an individual described in section 1396a(a)(10)(A) of this title, shall provide for payment of any coinsurance amounts imposed under section 1395e(a)(4) of this title.

...

PART 405--FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

FEDERALLY QUALIFIED HEALTH CENTER SERVICES

SOURCE: 57 FR 24978, June 12, 1992, unless otherwise noted.

§ 405.2430 Basic requirements.

(a) *Filing procedures.* (1) In response to a request from an entity that wishes to participate in the Medicare program, CMS enters into an agreement with an entity when—

- (i) PHS recommends that the entity qualifies as a Federally qualified health center;
- (ii) The Federally qualified health center assures CMS that it meets the Federally qualified health center requirements specified in this subpart and part 491, as described in § 405.2434(a); and
- (iii) The FQHC terminates other provider agreements, unless the FQHC assures CMS that it is not using the same space, staff and resources simultaneously as a physician's office or another type of provider or supplier. A corporate entity may own other provider types as long as the provider types are distinct from the FQHC.

(2) CMS sends the entity a written notice of the disposition of the request.

(3) When the requirement of paragraph (a)(1) of this section is satisfied, CMS sends the entity two copies of the agreement. The entity must sign and return both copies of the agreement to CMS.

(4) If CMS accepts the agreement filed by the Federally qualified health center, CMS returns to the center one copy of the agreement with the notice of acceptance specifying the effective date (see § 489.11), as determined under § 405.2434.

(b) *Recommendations by PHS about Federally qualified health centers.* (1) An entity must—

- (i) Meet the applicable requirements of the PHS Act, as specified in § 405.2401(b); and

- (ii) Be recommended by PHS to CMS as a Federally qualified health center.

(2) The PHS notifies CMS of entities that meet the requirements specified in § 405.2401(b).

(c) *Provider-based and freestanding Federally qualified health centers.* The requirements and benefits under Medicare for provider-based or freestanding Federally qualified health centers are the same, except that payment methodologies differ, as described in § 405.2462.

(d) *Appeals.* An entity is entitled to a hearing in accordance with part 498 of this chapter when CMS fails to enter into an agreement with the entity.

[57 FR 24978, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996]

§ 405.2434 Content and terms of the agreement.

Under the agreement, the Federally qualified health center must agree to the following:

(a) *Maintain compliance with the requirements.*

(1) The Federally qualified health center must agree to maintain compliance with the Federally qualified health center requirements set forth in this subpart and part 491, except that the provisions of § 491.3 do not apply.

(2) Centers must promptly report to CMS any changes that result in noncompliance with any of these requirements.

(b) *Effective date of agreement.* (1) Except as specified in paragraph (b)(2) of this section, the effective date of the agreement is the date CMS accepts the signed agreement, which assures that all Federal requirements are met.

(2) For facilities that met all requirements on October 1, 1991, the effective date of the agreement can be October 1, 1991.

(c) *Charges to beneficiaries.* (1) The beneficiary is responsible for payment of a coinsurance amount which is 20 percent of the amount of Part B payment made to the Federally qualified health center for the covered services. There is no coinsurance for a second or third opinion obtained in accordance with section 1164 of the Act or for pneumococcal vaccine and its administration.

(2) The beneficiary is responsible for blood deductible expenses, as specified in § 410.161.

(3) The Federally qualified health center agrees not to charge the beneficiary (or any other person acting on behalf of a beneficiary) for any Federally qualified health center services for which the beneficiary is entitled to have payment made on his or her behalf by the Medicare program (or for which the beneficiary would have been entitled if the Federally qualified health center had filed a request for payment in accordance with § 410.165 of this chapter), except for coinsurance amounts.

(4) The Federally qualified health center may charge the beneficiary for items and services that are not Federally qualified health center services. However, if the item or service is covered under Part B of Medicare, and the Federally qualified health center agrees to receive Part B payment under the assignment method, the Federally qualified health center may not charge the beneficiary more than 20 percent of the Part B payment.

(d) *Refunds to beneficiaries.* (1) The Federally qualified health center must agree to refund as promptly as possible any money incorrectly collected from Medicare beneficiaries or from someone on their behalf.

(2) As used in this section, “money incorrectly collected” means any amount for covered services that is greater than the amount for which the beneficiary was liable

because of the coinsurance requirements specified in part 410, subpart E.

(3) Amounts also are considered incorrectly collected if the Federally qualified health center believed the beneficiary was not entitled to Medicare benefits but—

(i) The beneficiary was later determined to have been so entitled;

(ii) The beneficiary’s entitlement period fell within the time the Federally qualified health center’s agreement with CMS was in effect; and

(iii) The amounts exceed the beneficiary’s coinsurance liability.

(e) *Treatment of beneficiaries.* (1) The Federally qualified health center must agree to accept Medicare beneficiaries for care and treatment.

(2) The Federally qualified health center may not impose any limitations with respect to care and treatment of Medicare beneficiaries that it does not also impose upon all other persons seeking care and treatment from the Federally qualified health center. Failure to comply with this requirement is a cause for termination of the Federally qualified health center’s agreement with CMS in accordance with § 405.2436(d).

(3) If the Federally qualified health center does not furnish treatment for certain illnesses and conditions to patients who are not Medicare beneficiaries, it need not furnish such treatment to Medicare beneficiaries.

§ 405.2436 Termination of agreement.

(a) *Termination by Federally qualified health center.* The Federally qualified health center may terminate its agreement by—

(1) Filing with CMS a written notice stating its intention to terminate the agreement; and

(2) Notifying CMS of the date on which the Federally qualified health center requests that the termination take effect.

(b) *Effective date.* (1) Upon receiving a

Federally qualified health center's notice of intention to terminate the agreement, CMS will set a date upon which the termination takes effect. This effective date may be—

(i) The date proposed by the Federally qualified health center in its notice of intention to terminate, if that date is acceptable to CMS; or

(ii) Except as specified in paragraph (2) of this section, a date set by CMS, which is no later than 6 months after the date CMS receives the Federally qualified health center's notice of intention to terminate.

(2) The effective date of termination may be less than 6 months following CMS's receipt of the Federally qualified health center's notice of intention to terminate if CMS determines that termination on such a date would not—

(i) Unduly disrupt the furnishing of Federally qualified health center services to the community; or

(ii) Otherwise interfere with the effective and efficient administration of the Medicare program.

(3) The termination is effective at the end of the last day of business as a Federally qualified health center.

(c) *Termination by CMS.* (1) CMS may terminate an agreement with a Federally qualified health center if it finds that the Federally qualified health center—

(i) No longer meets the requirements specified in this subpart; or

(ii) Is not in substantial compliance with—
(A) The provisions of the agreement; or
(B) The requirements of this subpart, any other applicable regulations of this part, or any applicable provisions of title XVIII of the Act.

(2) *Notice by CMS.* CMS will notify the Federally qualified health center in writing of its intention to terminate an agreement at least 15 days before the effective date stated in the written notice.

(3) *Appeal.* A Federally qualified health center may appeal CMS's decision to terminate the agreement in accordance with part 498 of this chapter.

(d) *Effect of termination.* When a Federally qualified health center's agreement is terminated whether by the Federally qualified health center or CMS, payment will not be available for Federally qualified health center services furnished on or after the effective date of termination.

§ 405.2440 Conditions for reinstatement after termination by CMS.

When CMS has terminated an agreement with a Federally qualified health center, CMS will not enter into another agreement with the Federally qualified health center to participate in the Medicare program unless CMS—

(a) Finds that the reason for the termination no longer exists; and

(b) Is assured that the reason for the termination of the prior agreement will not recur.

§ 405.2442 Notice to the public.

(a) When the Federally qualified health center voluntarily terminates the agreement and an effective date is set for the termination, the Federally qualified health center must notify the public prior to a prospective effective date or on the actual day that business ceases, if no prospective date of termination has been set, through publication in at least one newspaper in general circulation in the area serviced by the Federally qualified health center of the—

(1) Effective date of termination of the provision of services; and

(2) Effect of termination of the agreement.

(b) When CMS terminates the agreement, CMS will notify the public through publication in at least one newspaper in general circulation in the Federally qualified health center's service area.

§ 405.2444 Change of ownership.

(a) *What constitutes change of ownership*

—(1) *Incorporation*. The incorporation of an unincorporated FQHC constitutes change of ownership.

(2) *Merger*. The merger of the center corporation into another corporation, or the consolidation of two or more corporations, one of which is the center corporation, resulting in the creation of a new corporation, constitutes a change of ownership. (The merger of another corporation into the center corporation does not constitute change of ownership.)

(3) *Leasing*. The lease of all or part of an entity constitutes a change of ownership of the leased portion.

(b) *Notice to CMS*. A center which is contemplating or negotiating change of ownership must notify CMS.

(c) *Assignment of agreement*. When there is a change of ownership as specified in paragraph (a) of this section, the agreement with the existing center is automatically assigned to the new owner if it continues to meet the conditions to be a Federally qualified health center.

(d) *Conditions that apply to assigned agreements*. An assigned agreement is subject to all applicable statutes and regulations and to the terms and conditions under which it was originally issued including, but not limited to, the following:

(1) Compliance with applicable health and safety standards.

(2) Compliance with the ownership and financial interest disclosure requirements of part 420, subpart C of this subchapter.

§ 405.2446 Scope of services.

(a) For purposes of this section, the terms *rural health clinic* and *clinic* when they appear in the cross references in paragraph (b) of this section also mean Federally qualified health centers.

(b) FQHC services that are paid for under this subpart are outpatient services that include the following:

(1) Physician services specified in § 405.2412.

(2) Services and supplies furnished as an incident to a physician's professional services, as specified in § 405.2413.

(3) Nurse practitioner or physician assistant services specified in § 405.2414.

(4) Services and supplies furnished as an incident to a nurse practitioner or physician assistant services, as specified in § 405.2415.

(5) Clinical psychologist and **clinical social worker services** specified in § 405.2450.

(6) Services and supplies furnished as an incident to a clinical psychologist or **clinical social worker services**, as specified in § 405.2452.

(7) Visiting nurse services specified in § 405.2416.

(8) Nurse-midwife services specified in § 405.2401.

(9) Preventive primary services specified in § 405.2448 of this subpart.

(c) Federally qualified health center services are covered when provided in outpatient settings only, including a patient's place of residence, which may be a skilled nursing facility or a nursing facility or other institution used as a patient's home.

(d) Federally qualified health center services are not covered in a hospital, as defined in section 1861(e)(1) of the Act.

[57 FR 24979, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996]

§ 405.2448 Preventive primary services.

(a) Preventive primary services are those health services that—

(1) A center is required to provide as preventive primary health services under section 329, 330, and 340 of the Public Health Service Act;

(2) Are furnished by or under the direct supervision of a nurse practitioner, physician assistant, nurse midwife, specialized nurse practitioner, clinical psychologist, **clinical social worker**, or a physician;

(3) In the case of a service, are furnished by a member of the center's health care staff who is an employee of the center or by a physician under arrangements with the center; and

(4) Except as specifically provided in section 1861(s) of the Act, include only drugs and biologicals that cannot be self-administered.

(b) Preventive primary services which may be paid for when provided by Federally qualified health centers are the following:

(1) **Medical social services.**

(2) Nutritional assessment and referral.

(3) Preventive health education.

(4) Children's eye and ear examinations.

(5) Prenatal and post-partum care.

(6) Perinatal services.

(7) Well child care, including periodic screening.

(8) Immunizations, including tetanusdiphtheria booster and influenza vaccine.

(9) Voluntary family planning services.

(10) Taking patient history.

(11) Blood pressure measurement.

(12) Weight.

(13) Physical examination targeted to risk.

(14) Visual acuity screening.

(15) Hearing screening.

(16) Cholesterol screening.

(17) Stool testing for occult blood.

(18) Dipstick urinalysis.

(19) **Risk assessment and initial counseling regarding risks.**

(20) Tuberculosis testing for high risk patients.

(21) For women only.

(i) Clinical breast exam.

(ii) Referral for mammography; and

(iii) Thyroid function test.

(c) Preventive primary services do not include group or mass information programs, health education classes, or group education activities, including media productions and publications.

(d) Screening mammography is not considered a Federally qualified health center service, but may be provided at a Federally qualified health center if the center meets the requirements applicable to that service specified in § 410.34 of this subchapter. Payment is made under applicable Medicare requirements.

(e) Preventive primary services do not include eyeglasses, hearing aids, or preventive dental services.

[57 FR 24980, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996]

§ 405.2450 Clinical psychologist and clinical social worker services.

(a) For clinical psychologist or **clinical social worker professional services** to be payable under this subpart, the services must be—

(1) Furnished by an individual who owns, is employed by, or furnishes services under contract to the FQHC;

(2) Of a type that the clinical psychologist or clinical social worker who furnishes the services is legally permitted to perform by the State in which the service is furnished;

(3) Performed by a **clinical social worker** or clinical psychologist who is legally authorized to perform such services under State law or the State regulatory mechanism provided by the law of the State in which such services are performed; and

(4) Covered if furnished by a physician.

(b) If State law prescribes a physician supervision requirement, it is met if the conditions specified in § 491.8(b) of this chapter and any pertinent requirements of State law are satisfied.

(c) The services of clinical psychologists or **clinical social workers** are not covered if State law or regulations require that the services be performed under a physician's order and no such order was prepared.

[57 FR 24980, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996]

§ 405.2452 Services and supplies incident to clinical psychologist and clinical social worker services.

(a) Services and supplies incident to a clinical psychologist's or **clinical social worker's services** are reimbursable under this subpart if the service or supply is—

- (1) Of a type commonly furnished in a physician's office;
- (2) Of a type commonly furnished either without charge or included in the Federally qualified health center's bill;
- (3) Furnished as an incidental, although integral part of professional services furnished by a clinical psychologist or **clinical social worker**;
- (4) Furnished under the direct, personal supervision of a clinical psychologist, **clinical social worker** or physician; and
- (5) In the case of a service, furnished by a member of the center's health care staff who is an employee of the center.

(b) The direct personal supervision requirement in paragraph (a)(4) of this section is met only if the clinical psychologist or **clinical social worker** is permitted to supervise such services under the written policies governing the Federally qualified health center.

PAYMENT FOR RURAL HEALTH CLINIC AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES

SOURCE: 57 FR 24976, 24977, June 12, 1992, unless otherwise noted.

§ 405.2460 Applicability of general payment exclusions.

The payment conditions, limitations, and exclusions set out in subpart C of this part, part 410 and part 411 of this chapter are applicable to payment for services provided by rural health clinics and Federally qualified health centers, except that preventive primary services, as defined in § 405.2448, are covered in Federally qualified health centers and not excluded by the provisions of section 1862(a) of the Act.

§ 405.2462 Payment for rural health clinic and Federally qualified health center services.

(a) Payment to provider-based rural health clinics and Federally qualified health centers. A rural health clinic or Federally qualified health center is paid in accordance with parts 405 and 413 of this subchapter, as applicable, if:

- (1) The clinic or center is an integral and subordinate part of a hospital, skilled nursing facility or home health agency participating in Medicare (i.e., a provider of services); and

- (2) The clinic or center is operated with other departments of the provider under common licensure, governance and professional supervision.

(b) *Payment to independent rural health clinics and freestanding Federally qualified health centers.* (1) All other clinics and centers will be paid on the basis of an all-inclusive rate for each beneficiary visit for covered services. This rate will be determined by the intermediary, in accordance with this subpart and general instructions issued by CMS.

- (2) The amount payable by the intermediary for a visit will be determined in accordance with paragraph (b)(3) and (4) of this section.

(3) *Federally qualified health centers.* For Federally qualified health center visits, Medicare will pay 80 percent of the all-inclusive rate since no deductible is applicable to Federally qualified health center services.

- (4) *Rural health clinics.* (i) If the deductible has been fully met by the beneficiary prior to the rural health clinic visit, Medicare pays 80 percent of the all-inclusive rate.

- (ii) If the deductible has not been fully met by the beneficiary before the visit, and the amount of the clinic's reasonable customary charge for the services that is applied to the deductible is—

(A) Less than the all-inclusive rate, the amount applied to the deductible will be subtracted from the all-inclusive rate and 80 percent of the remainder, if any, will be paid to the clinic;

(B) Equal to or exceeds the all-inclusive rate, no payment will be made to the clinic.

(5) To receive payment, the clinic or center must follow the payment procedures specified in section 410.165 of this chapter.

(6) Payment for treatment of **mental psychoneurotic or personality disorders** is subject to the limitations on payment in § 410.155(c).

§ 405.2463 What constitutes a visit.

(a) *Visit.* (1) A visit is a face-to-face encounter between a clinic or center patient and a physician, physician assistant, nurse practitioner, nurse-midwife, or visiting nurse.

(2) For FQHCs, a visit also means a face-to-face encounter between a patient and a qualified clinical psychologist or **clinical social worker**.

(3) Encounters with more than one health professional and multiple encounters with the same health professional that take place on the same day and at a single location constitute a single visit, except when one of the following conditions exist:

(i) After the first encounter, the patient suffers illness or injury requiring additional diagnosis or treatment.

(ii) For FQHCs, the patient has a medical visit and an other health visit, as defined in paragraphs (b) and (c) of this section.

(4) *Payment.* (i) Medicare pays for two visits per day when the conditions in paragraph (a)(3) of this section are met.

(ii) In all other cases, payment is limited to one visit per day.

(b) *Medical visit.* For purposes of paragraph (a)(3) of this section, a medical visit is a face-to-face encounter between an FQHC patient and a physician, physician assistant,

nurse practitioner, nurse-midwife, or visiting nurse.

(c) *Other health visit.* For purposes of paragraph (a)(3) of this section, an other health visit is a face-to-face encounter between an FQHC patient and a clinical psychologist, **clinical social worker**, or other health professional for mental health services.

[61 FR 14657, Apr. 3, 1996]

§ 405.2464 All-inclusive rate.

(a) *Determination of rate.* (1) An all-inclusive rate is determined by the intermediary at the beginning of the reporting period.

(2) The rate is determined by dividing the estimated total allowable costs by estimated total visits for rural health clinic or Federally qualified health center services.

(3) The rate determination is subject to any tests of reasonableness that may be established in accordance with this subpart.

(b) *Adjustment of rate.* (1) The intermediary, during each reporting period, periodically reviews the rate to assure that payments approximate actual allowable costs and visits for rural health clinic or Federally qualified health center services and adjusts the rate if:

(i) There is a significant change in the utilization of clinic or center services;

(ii) Actual allowable costs vary materially from the clinic or center's allowable costs; or

(iii) Other circumstances arise which warrant an adjustment.

(2) The clinic or center may request the intermediary to review the rate to determine whether adjustment is required.

§ 405.2466 Annual reconciliation.

(a) *General.* Payments made to a rural health clinic or a Federally qualified health center during a reporting period are subject to reconciliation to assure that those payments do not exceed or fall short of the allowable costs attributable to covered services

furnished to Medicare beneficiaries during that period.

(b) *Calculation of reconciliation.* (1)

The total reimbursement amount due the clinic or center for covered services furnished to Medicare beneficiaries is based on the report specified in § 405.2470(c)(2) and is calculated by the intermediary as follows:

(i) The average cost per visit is calculated by dividing the total allowable cost incurred for the reporting period by total visits for rural health clinic or Federally qualified health center services furnished during the period. The average cost per visit is subject to tests of reasonableness which may be established in accordance with this subpart.

(ii) The total cost of rural health clinic or Federally qualified health center services furnished to Medicare beneficiaries is calculated by multiplying the average cost per visit by the number of visits for covered rural health clinic or Federally qualified health center services by beneficiaries.

(iii) For rural health clinics, the total reimbursement due the clinic is 80 percent of the amount calculated by subtracting the amount of deductible incurred by beneficiaries that is attributable to rural health clinic services from the cost of these services. The reimbursement computation for Federally qualified health centers does not include a reduction related to the deductible because Federally qualified health center services are not subject to a deductible.

(iv) For rural health clinics and FQHCs, payment for pneumococcal and influenza vaccine and their administration is 100 percent of Medicare reasonable cost.

(2) The total reimbursement amount due is compared with total payments made to the clinic or center for the reporting period, and the difference constitutes the amount of the reconciliation.

(c) *Notice of program reimbursement.* The intermediary sends written notice to the clinic or center:

(1) Setting forth its determination of the total reimbursement amount due the clinic or center for the reporting period and the amount, if any, of the reconciliation; and
(2) Informing the clinic or center of its right to have the determination reviewed at a hearing under the procedures set forth in subpart R of this part.

(d) *Payment of reconciliation amount—*

(1) *Underpayments.* If the total reimbursement due the clinic or center exceeds the payments made for the reporting period, the intermediary makes a lump-sum payment to the clinic or center to bring total payments into agreement with total reimbursement due the clinic or center.

(2) *Overpayments.* If the total payments made to a clinic or center for the reporting period exceed the total reimbursement due the clinic or center for the period, the intermediary arranges with the clinic or center for repayment through a lump-sum refund, or, if that poses a hardship for the clinic or center, through offset against subsequent payments or a combination of offset and refund. The repayment must be completed as quickly as possible, generally within 12 months from the date of the notice of program reimbursement. A longer repayment period may be agreed to by the intermediary if the intermediary is satisfied that unusual circumstances exist which warrant a longer period.

[57 FR 24976, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996]

§ 405.2468 Allowable costs.

(a) *Applicability of general Medicare principles.* In determining whether and to what extent a specific type or item of cost is allowable, such as interest, depreciation, bad debts and owner compensation, the intermediary applies the principles for

reimbursement of provider costs, as set forth in part 413 of this subchapter.

(b) *Typical rural health clinic and Federally qualified health center costs.* The following types and items of cost are included in allowable costs to the extent that they are covered and reasonable:

(1) Compensation for the services of a physician, physician assistant, nurse practitioner, nurse-midwife, visiting nurse, qualified clinical psychologist, and **clinical social worker** who owns, is employed by, or furnishes services under contract to an FQHC. (RHCs are not paid for services furnished by contracted individuals other than physicians.)

(2) Compensation for the duties that a supervising physician is required to perform under the agreement specified in § 491.8 of this chapter.

(3) Costs of services and supplies incident to the services of a physician, physician assistant, nurse practitioner, nurse-midwife, qualified clinical psychologist, or **clinical social worker**.

(4) Overhead costs, including clinic or center administration, costs applicable to use and maintenance of the entity, and depreciation costs.

(5) Costs of services purchased by the clinic or center.

(c) *Tests of reasonableness for rural health clinic cost and utilization.* Tests of reasonableness authorized by sections 1833(a) and 1861(v)(1)(A) of the Act may be established by CMS or the carrier with respect to direct or indirect overall costs, costs of specific items and services, or costs of groups of items and services. Those tests include, but are not limited to, screening guidelines and payment limitations.

(d) *Screening guidelines.* (1) Costs in excess of amounts established by the guidelines are not included unless the clinic or center provides reasonable justification satisfactory to the intermediary.

(2) Screening guidelines are used to assess the costs of services, including the following:

(i) Compensation for the professional and supervisory services of physicians and for the services of physician assistants, nurse practitioners, and nurse-midwives.

(ii) Services of physicians, physician assistants, nurse practitioners, nurse-midwives, visiting nurses, qualified clinical psychologists, and **clinical social workers**.

(iii) The level of administrative and general expenses.

(iv) Staffing (for example, the ratio of other clinic or center personnel to physicians, physician assistants, and nurse practitioners).

(v) The reasonableness of payments for services purchased by the clinic or center, subject to the limitation that the costs of physician services purchased by the clinic or center may not exceed amounts determined under the applicable provisions of subpart E of part 405 or part 415 of this chapter.

(e) *Payment limitations.* Limits on payments may be set by CMS, on the basis of costs estimated to be reasonable for the provision of such services.

(f) *Graduate medical education.* (1) Effective for that portion of cost reporting periods occurring on or after January 1, 1999, if an RHC or an FQHC incurs “all or substantially all” of the costs for the training program in the nonhospital setting as defined in § 413.86(b) of this chapter, the RHC or FQHC may receive direct graduate medical education payment for those residents.

(2) Direct graduate medical education costs are not included as allowable cost under § 405.2466(b)(1)(i); and therefore, are not subject to the limit on the all-inclusive rate for allowable costs.

(3) Allowable graduate medical education costs must be reported on the RHC’s or the

FQHC's cost report under a separate cost center.

(4) Allowable graduate medical education costs are non-reimbursable if payment for these costs are received from a hospital or a Medicare+Choice organization.

(5) Allowable direct graduate medical education costs under paragraphs (f)(6) and (f)(7)(i) of this section, are subject to reasonable cost principles under part 413 and the reasonable compensation equivalency limits in §§ 415.60 and 415.70 of this chapter.

(6) The allowable direct graduate medical education costs are those costs incurred by the nonhospital site for the educational activities associated with patient care services of an approved program, subject to the redistribution and community support principles in § 413.85(c).

(i) The following costs are allowable direct graduate medical education costs to the extent that they are reasonable —

(A) The costs of the residents' salaries and fringe benefits (including travel and lodging expenses where applicable).

(B) The portion of teaching physicians' salaries and fringe benefits that are related to the time spent teaching and supervising residents.

(C) Facility overhead costs that are allocated to direct graduate medical education.

(ii) The following costs are not allowable graduate medical education costs—

(A) Costs associated with training, but not related to patient care services.

(B) Normal operating and capital-related costs.

(C) The marginal increase in patient care costs that the RHC or FQHC experiences as a result of having an approved program.

(D) The costs associated with activities described in § 413.85(h) of this chapter.

(7) Payment is equal to the product of—

(i) The RHC's or the FQHC's allowable direct graduate medical education costs; and

(ii) Medicare's share, which is equal to the ratio of Medicare visits to the total number of visits (as defined in § 405.2463).

(8) Direct graduate medical education payments to RHCs and FQHCs made under this section are made from the Federal Supplementary Medical Insurance Trust Fund.

[43 FR 8261, Mar. 1, 1978. Redesignated and amended at 57 FR 24977, June 12, 1992; 60 FR 63176, Dec. 8, 1995; 61 FR 14658, Apr. 3, 1996; 63 FR 41002, July 31, 1998; 66 FR 39932, Aug. 1, 2001]

§ 405.2470 Reports and maintenance of records.

(a) *Maintenance and availability of records.* The rural health clinic or Federally qualified health center must:

(1) Maintain adequate financial and statistical records, in the form and containing the data required by CMS, to allow the intermediary to determine payment for covered services furnished to Medicare beneficiaries in accordance with this subpart;

(2) Make the records available for verification and audit by HHS or the General Accounting Office;

(3) Maintain financial data on an accrual basis, unless it is part of a governmental institution that uses a cash basis of accounting. In the latter case, appropriate depreciation on capital assets is allowable rather than the expenditure for the capital asset.

(b) *Adequacy of records.* (1) The intermediary may suspend reimbursement if it determines that the clinic or center does not maintain records that provide an adequate basis to determine payments under Medicare.

(2) The suspension continues until the clinic or center demonstrates to the intermediary's satisfaction that it does, and will continue to, maintain adequate records.

(c) *Reporting requirements*—(1) *Initial report*. At the beginning of its initial reporting period, the clinic or center must submit an estimate of budgeted costs and visits for rural health clinic or Federally qualified health center services for the reporting period, in the form and detail required by CMS, and such other information as CMS may require to establish the payment rate.

(2) *Annual reports*. Within 90 days after the end of its reporting period, the clinic or center must submit, in such form and detail as may be required by CMS, a report of:

(i) Its operations, including the allowable costs actually incurred for the period and the actual number of visits for rural health clinic or Federally qualified health center services furnished during the period; and

(ii) The estimated costs and visits for rural health clinic services or Federally qualified health center services for the succeeding reporting period and such other information as CMS may require to establish the payment rate.

(3) *Late reports*. If the clinic or center does not submit an adequate annual report on time, the intermediary may reduce or suspend payments to preclude excess payment to the clinic or center.

(4) *Inadequate reports*. If the clinic or center does not furnish a report or furnishes a report that is inadequate for the intermediary to make a determination of program payment, CMS may deem all payments for the reporting period to be overpayments.

(5) *Postponement of due date*. For good cause shown by the clinic or center, the intermediary may, with CMS's approval, grant a 30-day postponement of the due date for the annual report.

(6) *Reports following termination of agreement or change of ownership*. The report from a clinic or center which voluntarily or involuntarily ceases to participate in the Medicare program or

experiences a change in ownership (see §§ 405.2436–405.2438) is due no later than 45 days following the effective date of the termination of agreement or change of ownership.

§ 405.2472 Beneficiary appeals.

A beneficiary may request a hearing by an intermediary (subject to the limitations and conditions set forth in subpart H of this part) if:

(a) The beneficiary is dissatisfied with an intermediary's determination denying a request for payment made on his or her behalf by a rural health clinic or Federally qualified health center; or

(b) The beneficiary is dissatisfied with the amount of payment; or

(c) The beneficiary believes the request for payment is not being acted upon with reasonable promptness.

[43 FR 8261, Mar. 1, 1978. Redesignated and amended at 57 FR 24978, June 12, 1992]

Medicare Benefit Policy Manual
**CHAPTER 13 - RURAL HEALTH CLINIC (RHC) AND FEDERALLY QUALIFIED HEALTH
CENTER (FQHC) SERVICES**

20 - Federally Qualified Health Centers (FQHCs) Defined

(Rev. 1, 10-01-03)

§1861(aa), A3-3192.2 of the Act

A - General

Section 4161 of the Omnibus Budget Reconciliation Act (OBRA) of 1990 amended [§1861\(aa\)](#) of the Act to establish federally qualified health centers (FQHCs) as entities to provide a new Medicare benefit effective October 1, 1991. The statutory requirements that FQHCs must meet to qualify for the Medicare benefit are in [§1861\(aa\)\(4\)](#) of the Act. The FQHC services consist of services that are similar to those provided in rural health clinics (RHC). See [§30](#).

The FQHC services also include preventive primary health services. The law defines Medicare preventive services as the preventive primary health services that an FQHC is required to provide under [§330](#) of the Public Health Service (PHS) Act. Medicare may specifically not cover some of the preventive services that FQHCs currently provide. For example, the Medicare law contains exclusion for dental services that are, therefore, excluded from the FQHC benefit. No Part B deductible is applied to expenses for services that are payable under the FQHC benefit. The Medicare beneficiary is responsible for 20 percent of billed charges. Note that FQHCs can waive collection of all or part of the coinsurance, depending upon the beneficiary's ability to pay.

B - Special Requirements

An entity may qualify as an FQHC if it:

- Is receiving a grant under [§330](#) of the PHS Act; or
- Is receiving funding from such a grant under a contract with the recipient of a grant and meets the requirements to receive a grant under [§330](#) of the PHS Act; or
- Is determined by the Secretary to meet the requirements for receiving such a grant (look-alike) based on the recommendation of the Health Resources and Services Administration within PHS; or
- Is an outpatient health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act or by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act as of October 1, 1991.

Note that specific certification requirements are identified in the State Operations Manual.

An RHC cannot be concurrently approved for Medicare as both an FQHC and an RHC.

An entity that qualifies as an independent or provider-based FQHC is assigned an FQHC identification number in the provider number range 1800-1989. RHCs are assigned a provider number in the following ranges: provider-based ranges: 3975-3999, 3400-3499, 8500-8899; and independent ranges: 3800-3974, 8900-8999.

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30.2 - FQHC Services

(Rev. 1, 10-01-03)

RHC-400B

The FQHC services include all of the RHC services listed as included in §30.1 as well as preventive primary services, as described in §40.

The Medicare program makes payment directly to the FQHCs for covered services furnished to Medicare beneficiaries. The FQHC services are covered when furnished to a patient at the clinic or center, the patient's place of residence, or elsewhere (e.g., at the scene of an accident).

...

60.6 - Incident to Physician's Services in Physician-Directed RHC or FQHC

(Rev. 1, 10-01-03)

RHC-406.6

For purposes of the incident to provision, a physician-directed RHC or FQHC is one where:

- A physician (or a number of physicians) is present to perform medical (rather than administrative) services at all times the clinic or center is open;
- Each patient is under the care of a clinic or center physician; and
- The nonphysician services are under medical supervision.

In highly organized entities, particularly those which are departmentalized, direct personal physician supervision may be the responsibility of several physicians as opposed to an individual attending physician. In this situation, medical management of all services provided in the RHC or FQHC is assured. The physician ordering a particular service need not be the physician who is supervising the service. Therefore, services performed by therapists and other aides are covered even though they are performed in another department. Supplies provided by the clinic or center during the course of treatment are also covered. To be covered under Medicare as a service that is incident to a physician's service, the services of auxiliary personnel performed outside the clinic or center premises must be performed under the direct personal supervision of a clinic or center physician. If the clinic or center refers a patient for auxiliary services performed by personnel it does not employ, such services are not incident to a physician's service.

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110 - Clinical Social Worker (CSW) Services Away and at the RHC/FQHC Clinic or Center

(Rev. 1, 10-01-03)

RHC-419.2

(Rev. 1, 10-01-03)

RHC/FQHC services include the services provided by a clinical social worker.

110.1 - Clinical Social Worker Defined

(Rev. 1, 10-01-03)

RHC-419.2.A

A clinical social worker is an individual who:

- Possesses a master's or doctor's degree in social work;
- Has performed at least two years of supervised clinical social work; and
- Either:

- Is licensed or certified as a clinical social worker by the State in which the services are performed; or
- In the case of an individual in a State that does not provide for licensure or certification, has completed at least two years or 3,000 hours of post master's degree supervised clinical social work practice under the supervision of a master's level social worker in an appropriate setting such as a hospital, SNF, or clinic

110.2 - Clinical Social Worker Services Defined

(Rev. 1, 10-01-03)

RHC-419.2.B

Clinical social worker services for the diagnosis and treatment of mental illnesses and services and supplies furnished incident to such services are covered as long as the CSW is legally authorized to perform them under State law (or the State regulatory mechanism provided by State law) of the State in which such services are performed. The services that are covered are those that are otherwise covered if furnished by a physician or as an incident to a physician's professional service. Services furnished to an inpatient or outpatient that a hospital is required to provide as a requirement for participation are not included.

110.3 - Covered CSW Services

(Rev. 1, 10-01-03)

RHC-419.2.C

Clinical social worker services and supplies furnished incident to such services are covered as the services furnished by a physician or as incident to physician's services are covered. (See §60.) Coverage is limited to the services a CSW is legally authorized to perform in accordance with State law, including services and supplies furnished incident to such services and are those that are otherwise covered if furnished by a physician or incident to a physician's professional service. The services of a CSW may be covered in an RHC/FQHC if they are:

- The type of services that are otherwise covered if furnished by a physician, or incident to a physician's service;
- Performed by a person who meets the above definition of a CSW; and Not otherwise excluded from coverage.
- State law or regulatory mechanism governing a CSW's scope of practice in the service area must be considered. Development of a list of services within the scope of practice is encouraged.

110.4 - Noncovered CSW Services

(Rev. 1, 10-01-03)

CSW services are not covered if they are otherwise excluded from Medicare coverage even though a CSW is authorized by State law to perform them. For example, the Medicare law excludes from coverage services that are not "reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member."

110.5 - Outpatient Mental Health Services Limitation

(Rev. 1, 10-01-03)

All covered therapeutic services furnished by qualified CSWs are subject to the outpatient psychiatric services limitation (i.e., only 62 1/2 percent of expenses for these services are considered incurred expenses for Medicare purposes). The limitation does not apply to diagnostic services.

110.6 - Services at the Clinic or Center

(Rev. 1, 10-01-03)

RHC-419.2.F

The services of clinical social workers performed at the clinic or center are RHC or FQHC services and are payable only to the clinic or center.

110.7 - Services Away From the Clinic or Center

(Rev. 1, 10-01111-03)

RHC-419.2.G

Clinical social workers who are employees of an RHC or FQHC, or who are compensated by the clinic or center for providing services furnished to clinic or center patients in a location other than at the clinic/center facility, may furnish services to clinic/center patients at the clinic/center facility or in other locations, such as in a patient's home. These services are RHC/FQHC services and are reimbursable only to the clinic or center.

A clinical social worker that is compensated by the clinic/center for services in locations other than the clinic/center, may not bill the Medicare program through the carrier for services furnished to Medicare beneficiaries who are clinic/center patients, regardless of place of service.

State Medicaid Manual

Part 4 - Services

04-90

REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

4231

4231. FEDERALLY QUALIFIED HEALTH CENTER (FQHC) AND OTHER AMBULATORY SERVICES

A. Background.--Section 6404 of the Omnibus Budget Reconciliation Act of 1989 (P.L. 101-239) amended §§1905(a) and (l) of the Social Security Act to provide for coverage and definition of Federally Qualified Health Center (FQHC) services and other ambulatory services offered by an FQHC under Medicaid. Payment for services added by §6404 is effective for services provided on or after April 1, 1990. Payment for FQHC services is discussed in §6303.

B. FQHC Services and Other Ambulatory Services.--FQHC services are defined the same as the services provided by rural health clinics (RHCs) and generally described as RHC services. These services include physician services, services provided by physician assistants, nurse practitioners, clinical psychologists, **clinical social workers**, and services and supplies incident to such services as would otherwise be covered if furnished by a physician or as an incident to a physician's services. In certain cases, services to a homebound Medicaid patient may be provided. For a discussion of RHC services, see the Medicare Rural Health Clinic Manual, Chapter IV. Any other ambulatory service included in a State's Medicaid plan is considered a covered FQHC service, if the FQHC offers such a service.

C. Qualified FQHCs.--FQHCs are facilities or programs more commonly known as Community Health Centers, Migrant Health Centers, and Health Care for the Homeless Programs. For purposes of providing covered services under Medicaid, FQHCs may qualify as follows:

- The facility receives a grant under §§329, 330, or 340 of the Public Health Service (PHS) Act;
- The Health Resources and Services Administration (HRSA) within the PHS recommends, and the Secretary determines that, the facility meets the requirements for receiving such a grant; or
- The Secretary determines that a facility may, for good cause, qualify through waivers of the requirements described above. Such a waiver cannot exceed a period of 2 years.
- A list of facilities receiving grants under §§329, 330, and 340, and thereby automatically qualified for provision of and payment for services provided under this section, is found in Exhibit
- Immediately following this section. The PHS advises HCFA timely of changes in status of grantees and other qualified FQHCs.

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5600 Fishers Lane
Rockville, MD 20857

D. Effective Date.--April 1, 1990 is the effective date for services provided under §6404 of OBRA-89. Submit State plan amendments to the HCFA regional offices no later than June 30, 1990, in order to obtain approval for services provided on or after the effective date. However, when the Secretary determines that State legislation (other than for funding) is necessary in order for the plan to meet the additional requirements of §6404, the State plan is out of compliance only if it fails to comply with such additional requirements after the first day of the first calendar quarter beginning after the close of the first regular session of a State legislature that begins after the date of the enactment of OBRA-89 (December 19, 1989). In a State that has a 2 year legislative session each year of the session is deemed to be a separate regular session of the State legislature.

State Medicaid Manual
Part 6 – Payment for Services

04-90

PAYMENT FOR SERVICE

6303

**6303. FEDERALLY QUALIFIED HEALTH CENTER AND OTHER
AMBULATORY SERVICES PAYMENT**

Pay 100 percent of the costs which are reasonable and related to the cost of furnishing Federally Qualified Health Center (FQHC) services and other ambulatory services defined in §1905(a)(2)(C) of the Social Security Act. The State payment system may utilize prospectively determined payment rates or may pay interim rates subject to reconciliation at the end of a cost reporting period. Irrespective of the type of payment method utilized, the State must determine and assure that the payments are based upon, and cover, the reasonable costs of providing services to Medicaid beneficiaries. Such costs cannot exceed the reasonable costs as determined by the applicable Medicare cost reimbursement principles set forth in 42 CFR Part 413. Other standards of reasonableness will be developed through regulation. Additional information will be provided when regulations are published in the Federal Register.

This is in accordance with §6404 of the Omnibus Budget Reconciliation Act of 1989, P.L. 101-239, which amends §1902(a)(13)(E) of the Social Security Act.

MEDICARE PART A AND PART B
(Benefits Covered under Both Part A and Part B)

RISK-SHARING HEALTH MAINTENANCE ORGANIZATIONS AND COMPETITIVE MEDICAL PLANS—CLINICAL SOCIAL WORK SERVICES/CLINICAL SOCIAL WORKER

A major breakthrough for the reimbursement of clinical social workers under Medicare Part B came with the passage of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87). Specifically, OBRA '87 provided coverage for clinical social workers in risk-sharing health maintenance organizations (HMOs) and competitive medical plans (CMPs)¹³ as autonomous providers, effective January 1, 1988.

Before OBRA '87, HMOs and CMPs had to make available to their enrollees the full range of Medicare-covered services and could provide additional services not ordinarily covered. At the time, this included the services of a clinical social worker, although such services had to be under the supervision of a physician. With the passage of the OBRA '87 provision, the services of clinical social workers were covered without requirement of physician supervision, and services and supplies incident to such services if a physician would otherwise provide the services.

For the first time, Medicare law included clinical social workers as autonomous mental health providers. The law also established educational and experience criteria that required a master's or doctoral degree in social work, at least two years of supervised clinical social work, and licensure or certification by the state in which the services are to be performed. In states that do not provide for licensure or certification, the individual must have completed two years or 3,000 hours of post-master's degree supervised clinical social work in an appropriate setting. These same qualification requirements now apply to the definition of clinical social worker under the new Medicare Part B provision that became effective as a result of OBRA '89.

With the inclusion of clinical social worker services as a covered service under Medicare Part B, risk-sharing HMOs and CMPs are now required to provide such services. (See "Outpatient Mental Health Services.")

¹³ Competitive medical plans are HMO—like prepayment organizations that do not meet all HMO standards, but that qualify for HMO—type reimbursement. The statute refers to both as "eligible organizations."

SOCIAL SECURITY ACT § 1861

42USC1395x

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part D--Miscellaneous Provisions

Sec. 1395x. Definitions

For purposes of this subchapter--

...

(s) Medical and other health services

The term ``medical and other health services'' means any of the following items or services:

(1) physicians' services;

(2)

.....

(E) rural health clinic services and Federally qualified health center services;

.....

(H)(i) services furnished pursuant to a contract under section 1395mm of this title to a member of an eligible organization by a physician assistant or by a nurse practitioner (as defined in subsection (aa)(5) of this section) and such services and supplies furnished as an incident to his service to such a member as would otherwise be covered under this part if furnished by a physician or as an incident to a physician's service; and

(ii) services furnished pursuant to a risk-sharing contract under section 1395mm(g) of this title to a member of an eligible organization by a clinical psychologist (as defined by the Secretary) or by a **clinical social worker** (as defined in subsection (hh)(2) of this section), and such services and supplies furnished as an incident to such clinical psychologist's services or **clinical social worker's services** to such a member as would otherwise be covered under this part if furnished by a physician or as an incident to a physician's service;

.....

(N) **clinical social worker services** (as defined in subsection (hh)(2) of this section);

.....

(aa) Rural health clinic services and Federally qualified health center services

(1) The term ``rural health clinic services'' means--

(A) physicians' services and such services and supplies as are covered under subsection (s)(2)(A) of this section if furnished as an incident to a physician's professional service and items and services described in subsection (s)(10) of this section,

(B) such services furnished by a physician assistant or a nurse practitioner (as defined in paragraph (5)), by a clinical psychologist (as defined by the Secretary) or by a **clinical social worker** (as defined in subsection (hh)(1) of this section),\8\ and such services and supplies furnished as an incident to his service as would otherwise be covered if furnished by a physician or as an incident to a physician's service, and

\8\ So in original.

.....

(hh) **Clinical social worker; clinical social worker services -**

- (1) The term ``clinical social worker" means an individual who--
- (A) possesses a master's or doctor's degree in social work;
 - (B) after obtaining such degree has performed at least 2 years of supervised clinical social work; and
 - (C)(i) is licensed or certified as a clinical social worker by the State in which the services are performed, or
 - (ii) in the case of an individual in a State which does not provide for licensure or certification--
 - (I) has completed at least 2 years or 3,000 hours of post-master's degree supervised clinical social work practice under the supervision of a master's level social worker in an appropriate setting (as determined by the Secretary), and
 - (II) meets such other criteria as the Secretary establishes.

(2) The term ``clinical social worker services" means services performed by a clinical social worker (as defined in paragraph (1)) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital and other than services furnished to an inpatient of a skilled nursing facility which the facility is required to provide as a requirement for participation) which the clinical social worker is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are performed as would otherwise be covered if furnished by a physician or as an incident to a physician's professional service.

...

SOCIAL SECURITY ACT § 1876

42USC1395mm

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part D--Miscellaneous Provisions

Sec. 1395mm. Payments to health maintenance organizations and competitive medical plans

...

(c) Enrollment in plan; duties of organization to enrollees

(1) The Secretary may not enter into a contract under this section with an eligible organization unless it meets the requirements of this subsection and subsection (e) of this section with respect to members enrolled under this section.

(2)(A) The organization must provide to members enrolled under this section, through providers and other persons that meet the applicable requirements of this subchapter and part A of subchapter XI of this chapter--

(i) only those services covered under parts A and B of this subchapter, for those members entitled to benefits under part A of this subchapter and enrolled under part B of this subchapter, or

(ii) only those services covered under part B of this subchapter, for those members enrolled only under such part,

which are available to individuals residing in the geographic area served by the organization, except that (I) the organization may provide such members with such additional health care services as the members may elect, at their option, to have covered, and (II) in the case of an organization with a risk-sharing contract, the organization may provide such members with such additional health care services as the Secretary may approve. The Secretary shall approve any such additional health care services which the organization proposes to offer to such members, unless the Secretary determines that including such additional services will substantially discourage enrollment by covered individuals with the organization.

(B) If there is a national coverage determination made in the period beginning on the date of an announcement under subsection (a)(1)(A) of this section and ending on the date of the next announcement under such subsection that the Secretary projects will result in a significant \2\ change in the costs to the organization of providing the benefits that are the subject of such national coverage determination and that was not incorporated in the determination of the per capita rate of payment included in the announcement made at the beginning of such period--

\2\ So in original. Probably should be ``significant".

(i) such determination shall not apply to risk-sharing contracts under this section until the first contract year that begins after the end of such period; and

(ii) if such coverage determination provides for coverage of additional benefits or under additional circumstances, subsection (a)(3) of this section shall not apply to payment for such additional benefits or benefits provided under such additional circumstances until the first contract year that begins after the end of such period, unless otherwise required by law.

...

PART 417--HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

Subpart A—General Provisions

§ 417.1 Definitions.

As used in this part, unless the context indicates otherwise—

Basic health services means health services described in § 417.101(a).

Community rating system means a system of fixing rates of payments for health services that meets the requirements of § 417.104(a)(3).

Comprehensive health services means as a minimum the following services which may be limited as to time and cost:

- (1) Physician services (§ 417.101(a)(1));
- (2) Outpatient services and inpatient hospital services (§ 417.101(a)(2));
- (3) Medically necessary emergency health services (§ 417.101(a)(3)); and
- (4) Diagnostic laboratory and diagnostic and therapeutic radiologic services (§ 417.101(a)(6)).

Direct service contract means a contract for the provision of basic or supplemental health services or both between an HMO and (1) a health professional other than a member of the staff of the HMO, or (2) an entity other than a medical group or an IPA.

Enrollee means an individual for whom an HMO, CMP, or HCPP assumes the responsibility, under a contract or agreement, for the furnishing of health care services on a prepaid basis.

Full-time student means a student who is enrolled for a sufficient number of credit hours in a semester or other academic term to enable the student to complete the course of study within not more than the number of semesters or other academic terms normally required to complete that course of study on a full-time basis at the school in which the student is enrolled.

Furnished, when used in connection with prepaid health care services, means services that are made available to an enrollee either

directly by, or under arrangements made by, the HMO, CMP, or HCPP.

Health maintenance organization (HMO) means a legal entity that provides or arranges for the provision of basic and supplemental health services to its enrollees in the manner prescribed by, is organized and operated in the manner prescribed by, and otherwise meets the requirements of, section 1301 of the PHS Act and the regulations in subparts B and C of this part.

Health professionals means physicians (doctors of medicine and doctors of osteopathy), dentists, nurses, podiatrists, optometrists, physicians' assistants, clinical psychologists, **social workers**, pharmacists, nutritionists, occupational therapists, physical therapists, and other professionals engaged in the delivery of health services who are licensed, practice under an institutional license, are certified, or practice under authority of the HMO, a medical group, individual practice association, or other authority consistent with State law.

Individual practice association (IPA) means a partnership, association, corporation, or other legal entity that delivers or arranges for the delivery of health services and which has entered into written services arrangement or arrangements with health professionals, a majority of whom are licensed to practice medicine or osteopathy.

The written services arrangement must provide:

- (1) That these health professionals will provide their professional services in accordance with a compensation arrangement established by the entity; and
- (2) To the extent feasible, for the sharing by these health professionals of health (including medical) and other records, equipment, and professional, technical, and administrative staff.

Medical group means a partnership, association, corporation, or other group:

(1) That is composed of health professionals licensed to practice medicine or osteopathy and of such other licensed health professionals (including dentists, optometrists, and podiatrists) as are necessary for the provision of health services for which the group is responsible;

(2) A majority of the members of which are licensed to practice medicine or osteopathy; and

(3) The members of which: (i) After the end of the 48 month period beginning after the month in which the HMO for which the group provides health services becomes a qualified HMO, as their principal professional activity (over 50 percent individually) engage in the coordinated practice of their profession and as a group responsibility have substantial responsibility (over 35 percent in the aggregate of their professional activity) for the delivery of health services to enrollees of an HMO;

(ii) Pool their income from practice as members of the group and distribute it among themselves according to a prearranged salary or drawing account or other similar plan unrelated to the provision of specific health services;

(iii) Share health (including medical) records and substantial portions of major equipment and of professional, technical, and administrative staff;

(iv) Establish an arrangement whereby an enrollee's enrollment status is not known to the health professional who provides health services to the enrollee

Medical group members means (1) a health professional engaged as a partner, associate, or shareholder in the medical group, or (2) any other health professional employed by the group who may be designated as a medical group member by the medical group.

Medically underserved population means the population of an urban or rural area as described in Sec. 417.912(d).

Nonmetropolitan area means an area no part of which is within a standard metropolitan statistical area as designated by the Office of

Management and Budget and which does not contain a city whose population exceeds 50,000 individuals.

Party in interest means: (1) Any director, officer, partner, or employee responsible for management or administration of an HMO, any person who is directly or indirectly the beneficial owner of more than 5 percent of the equity of the HMO, any person who is the beneficial owner of a mortgage, deed of trust, note, or other interest secured by, and valuing more than 5 percent of the assets of the HMO, and, in the case of an HMO organized as a nonprofit corporation, an incorporator or member of the corporation under applicable State corporation law;

(2) Any entity in which a person described in paragraph (1):

(i) Is an officer or director;

(ii) Is a partner (if the entity is organized as a partnership);

(iii) Has directly or indirectly a beneficial interest of more than 5 percent of the equity; or

(iv) Has a mortgage, deed of trust, note, or other interest valuing more than 5 percent of the assets of such entity;

(3) Any spouse, child, or parent of an individual described in paragraph (1).

Policymaking body of an HMO means a board of directors, governing body, or other body of individuals that has the authority to establish policy for the HMO.

Qualified HMO means an HMO found by CMS to be qualified within the meaning of section 1310 of the PHS Act and subpart D of this part.

Rural area means any area not listed as a place having a population of 2,500 or more in Document #PC(1)A, "Number of Inhabitants," Table VI, "Population of Places," and not listed as an urbanized area in Table XI, "Population of Urbanized Areas" of the same document (1970 Census or most recent update of this document, Bureau of Census, U.S. Department of Commerce).

Secretary means the Secretary of Health and Human Services and any other officer or

employee of the Department of Health and Human Services to whom the authority involved has been delegated.

Service area means a geographic area, defined through zip codes, census tracts, or other geographic measurements, that is the area, as determined by CMS, within which the HMO furnishes basic and supplemental health services and makes them available and accessible to all its enrollees in accordance with § 417.106(b).

Significant business transaction means any business transaction or series of transactions during any one fiscal year of the HMO, the total value of which exceeds the lesser of \$25,000 or 5 percent of the total operating expenses of the HMO.

Staff of the HMO means health professionals who are employees of the HMO and who—

- (1) Provide services to HMO enrollees at an HMO facility subject to the staff policies and operational procedures of the HMO;
- (2) Engage in the coordinated practice of their profession and provide to enrollees of the HMO the health services that the HMO has contracted to provide;
- (3) Share medical and other records, equipment, and professional, technical, and administrative staff of the HMO; and
- (4) Provide their professional services in accordance with a compensation arrangement, other than fee-for-service, established by the HMO. This arrangement may include, but is not limited to, fee-for-time, retainer or salary.

Subscriber means an enrollee who has entered into a contractual relationship with the HMO or who is responsible for making payments for basic health services (and contracted for supplemental health services) to the HMO or on whose behalf these payments are made.

Supplemental health services means the health services described in § 417.102(a).

Unusual or infrequently used health services means:

- (1) Those health services that are projected to involve fewer than 1 percent of the encounters per year for the entire HMO enrollment, or,

- (2) Those health services the provision of which, given the enrollment projection of the HMO and generally accepted staffing patterns, is projected will require less than 0.25 full time equivalent health professionals. [45 FR 72528, Oct. 31, 1980, as amended at 47 FR 19338, May 5, 1982; 52 FR 22321, June 11, 1987. Redesignated at 52 FR 36746, Sept. 30, 1987. Redesignated and amended at 56 FR 51985, Oct. 17, 1991; 58 FR 38067, July 15, 1993; 60 FR 34887, July 5, 1995; 60 FR 45674, Sept. 1, 1995]

§ 417.2 Basis and scope.

(a) Subparts B through F of this part pertain to the Federal qualification of HMOs under title XIII of the Public Health Service (PHS) Act.

(b) Subparts G through R of this part set forth the rules for Medicare contracts with, and payment to, HMOs and competitive medical plans (CMPs) under section 1876 of the Act.

(c) Subpart U of this part pertains to Medicare payment to health care prepayment plans under section 1833(a)(1)(A) of the Act.

(d) Subpart V of this part applies to the administration of outstanding loans and loan guarantees previously granted under title XIII of the PHS Act.

[56 FR 51985, Oct. 17, 1991, as amended at 60 FR 45675, Sept. 1, 1995]

Subpart B—Qualified Health Maintenance Organizations: Services **§ 417.101 Health benefits plan: Basic health services.**

(a) An HMO must provide or arrange for the provision of basic health services to its enrollees as needed and without limitations as to time and cost other than those prescribed in the PHS Act and these regulations, as follows:

(1) Physician services (including consultant and referral services by a physician), which must be provided by a licensed physician, or if a service of a physician may also be provided under applicable State law by other health professionals, an HMO may provide the service through these other health professionals;

(2)(i) Outpatient services, which must include diagnostic services, treatment services and x-

ray services, for patients who are ambulatory and may be provided in a non-hospital based health care facility or at a hospital;

(ii) Inpatient hospital services, which must include but not be limited to, room and board, general nursing care, meals and special diets when medically necessary, use of operating room and related facilities, use of intensive care unit and services, x-ray services, laboratory, and other diagnostic tests, drugs, medications, biologicals, anesthesia and oxygen services, special duty nursing when medically necessary, radiation therapy, inhalation therapy, and administration of whole blood and blood plasma;

(iii) Outpatient services and inpatient hospital services must include short-term rehabilitation services and physical therapy, the provision of which the HMO determines can be expected to result in the significant improvement of a member's condition within a period of two months;

(3) Instructions to its enrollees on procedures to be followed to secure medically necessary emergency health services both in the service area and out of the service area;

(4) Twenty outpatient visits per enrollee per year, as may be necessary and appropriate for short-term evaluative or crisis intervention mental health services, or both;

(5) Diagnosis, medical treatment and referral services (including referral services to appropriate ancillary services) for the abuse of or addiction to alcohol and drugs:

(i) Diagnosis and medical treatment for the abuse of or addiction to alcohol and drugs must include detoxification for alcoholism or drug abuse on either an outpatient or inpatient basis, whichever is medically determined to be appropriate, in addition to the other required basic health services for the treatment of other medical conditions;

(ii) Referral services may be either for medical or for nonmedical ancillary services. Medical services must be a part of basic health services; nonmedical ancillary services (such as vocational rehabilitation and employment counseling) and prolonged

rehabilitation services in a specialized inpatient or residential facility need not be a part of basic health services;

(6) Diagnostic laboratory and diagnostic and therapeutic radiologic services in support of basic health services;

(7) Home health services provided at an enrollee's home by health care personnel, as prescribed or directed by the responsible physician or other authority designated by the HMO; and

(8) Preventive health services, which must be made available to members and must include at least the following:

(i) A broad range of voluntary family planning services;

(ii) Services for infertility;

(iii) Well-child care from birth;

(iv) Periodic health evaluations for adults;

(v) Eye and ear examinations for children through age 17, to determine the need for vision and hearing correction; and

(vi) Pediatric and adult immunizations, in accord with accepted medical practice.

(b) In addition, an HMO may include a health service described in § 417.102 as a supplemental health service in the basic health services that it provides or arranges for its enrollees for a basic health services payment.

(c) To the extent that a natural disaster, war, riot, civil insurrection, epidemic or any other emergency or similar event not within the control of an HMO results in the facilities, personnel, or financial resources of an HMO being unavailable to provide or arrange for the provision of a basic or supplemental health service in accordance with the requirements of §§ 417.101 through 417.106 and §§ 417.168 and 417.169, the HMO is required only to make a good-faith effort to provide or arrange for the provision of the service, taking into account the impact of the event. For purposes of this paragraph, an event is not within the control of an HMO if the HMO cannot exercise influence or dominion over its occurrence.

(d) The following are **not required to be provided as basic health services**:

- (1) Corrective appliances and artificial aids;
 - (2) **Mental health services, except as required under section 1302(1)(D) of the PHS Act and paragraph (a)(4) of this section;**
 - (3) Cosmetic surgery, unless medically necessary;
 - (4) Prescribed drugs and medicines incidental to outpatient care;
 - (5) Ambulance services, unless medically necessary;
 - (6) Care for military service connected disabilities for which the enrollee is legally entitled to services and for which facilities are reasonably available to this enrollee;
 - (7) Care for conditions that State or local law requires be treated in a public facility;
 - (8) Dental services;
 - (9) Vision and hearing care except as required by sections 1302(1)(A) and 1302(1)(H)(vi) of the PHS Act and paragraphs (a)(1) and (a)(8) of this section;
 - (10) Custodial or domiciliary care;
 - (11) Experimental medical, surgical, or other experimental health care procedures, unless approved as a basic health service by the policymaking body of the HMO;
 - (12) Personal or comfort items and private rooms, unless medically necessary during inpatient hospitalization;
 - (13) Whole blood and blood plasma;
 - (14) Long-term physical therapy and rehabilitation;
 - (15) Durable medical equipment for home use (such as wheel chairs, surgical beds, respirators, dialysis machines); and
 - (16) Health services that are unusual and infrequently provided and not necessary for the protection of individual health, as approved by CMS upon application by the HMO.
- (e) An HMO may not offer to provide or arrange for the provision of basic health services on a prepayment basis that do not include all the basic health services set forth in paragraph (a) of this section or that are limited as to time and cost except in a manner prescribed by this subpart.

[45 FR 72528, Oct. 31, 1980. Redesignated at 52 FR 36746, Sept. 30, 1987, and amended at 58 FR 38077, July 15, 1993]

§ 417.102 Health benefits plan:

Supplemental health services.

(a) An HMO may provide to its enrollees any health service that is not included as a basic health service under § 417.101(a). These health services may be limited as to time and cost.

(b) An HMO must determine the level and scope of supplemental health services included with basic health services provided to its enrollees for a basic health services payment or those services offered to its enrollees as supplemental health services.

[45 FR 72528, Oct. 31, 1980, as amended at 47 FR 19339, May 5, 1982. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 58 FR 38082, 38083, July 15, 1993]

§ 417.103 Providers of basic and supplemental health services.

(a)(1) The HMO must provide that the services of health professionals that are provided as basic health services will, except as provided in paragraph (c) of this section, be provided or arranged for through (i) health professionals who are staff of the HMO, (ii) a medical group or groups, (iii) an IPA or IPAs, (iv) physicians or other health professionals under direct service contracts with the HMO for the provision of these services, or (v) any combination of staff, medical group or groups, IPA or IPAs, or physicians or other health professionals under direct service contracts with the HMO.

(2) A staff or medical group model HMO may have as providers of basic health services physicians who have also entered into written services arrangements with an IPA or IPAs, but only if either (i) these physicians number less than 50 percent of the physicians who have entered into arrangements with the IPA or IPAs, or (ii) if the sharing is 50 percent or greater, CMS approves the sharing as being consistent with the purposes of section 1310(b) of the PHS Act.

(3) After the 4 year period beginning with the month following the month in that an HMO becomes a qualified HMO, an entity that meets the requirements of the definition of medical group in § 417.100, except for subdivision (3)(i) of that definition, may be considered a medical group if CMS determines that the principal professional activity (over 50 percent individually) of the entity's members is the coordinated practice of their profession, and if the HMO has demonstrated to the satisfaction of CMS that the entity is committed to the delivery of medical services on a prepaid group practice basis by either:

(i) Presenting a reasonable timephased plan for the entity to achieve compliance with the "substantial responsibility" requirement of subdivision (3)(i) of the definition of "medical group" in § 417.100. The HMO must update the plan annually and must demonstrate to the satisfaction of CMS that the entity is making continuous efforts and progress towards compliance with the requirements of the definition of "medical group," or

(ii) Demonstrating that compliance by the entity with the "substantial responsibility" requirement is unreasonable or impractical because (A) the HMO serves a non-metropolitan or rural area as defined in § 417.100, or (B) the entity is a multi-speciality group that provides medical consultation upon referral on a regional or national basis, or (C) the majority of the residents of the HMO's service area are not eligible for employer-employee health benefits plans and the HMO has an insufficient number of enrollees to require utilization of at least 35 percent of the entity's services.

(b) HMOs must have effective procedures to monitor utilization and to control cost of basic and supplemental health services and to achieve utilization goals, which may include mechanisms such as risk sharing, financial incentives, or other provisions agreed to by providers.

(c) Paragraph (a) of this section does not apply to the provision of the services of a physician:

(1) Which the HMO determines are unusual or infrequently used services; or

(2) Which, because of an emergency, it was medically necessary to provide to the enrollee other than as required by paragraph (a) of this section; or

(3) Which are provided as part of the inpatient hospital services by employees or staff of a hospital or provided by staff of other entities such as **community mental health centers**, home health agencies, visiting nurses' associations, independent laboratories, or family planning agencies.

(d) Supplemental health services must be provided or arranged for by the HMO and need not be provided by providers of basic health services under contract with the HMO.

(e) Each HMO must:

(1) Pay the provider, or reimburse its enrollees for the payment of reasonable charges for basic health services (or supplemental health services that the HMO agreed to provide on a prepayment basis) for which its enrollees have contracted, which were medically necessary and immediately required to be obtained other than through the HMO because of an unforeseen illness, injury, or condition, as determined by the HMO;

(2) Adopt procedures to review promptly all claims from enrollees for reimbursement for the provision of health services described in paragraph (e)(1) of this section, including a procedure for the determination of the medical necessity for obtaining the services other than through the HMO; and

(3) Provide instructions to its enrollees on procedures to be followed to secure these health services. (Sec. 215 of the Public Health Service Act, as amended, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); secs. 1301–1318, as amended, Pub. L. 97–35, 95 Stat. 572–578 (42 U.S.C. 300e–300e–17) [45 FR 72528, Oct. 31, 1980; 45 FR 77031, Nov. 21, 1980, as amended at 47 FR 19339, May 5, 1982; 50 FR 6174, Feb. 14, 1985.]

Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 58 FR 38082, 38083, July 15, 1993]

§ 417.104 Payment for basic health services.

(a) *Basic health services payment.* Each HMO must provide or arrange for the provision of basic health services for a basic health services payment that:

- (1) Is to be paid on a periodic basis without regard to the dates these services are provided;
 - (2) Is fixed without regard to the frequency, extent, or kind of basic health services actually furnished;
 - (3) Except as provided in paragraph (c) of this section, is fixed under a community rating system, as described in paragraph (b) of this section; and
 - (4) May be supplemented by nominal copayments which may be required for the provision of specific basic health services. Each HMO may establish one or more copayment options calculated on the basis of a community rating system.
 - (i) An HMO may not impose copayment charges that exceed 50 percent of the total cost of providing any single service to its enrollees, nor in the aggregate more than 20 percent of the total cost of providing all basic health services.
 - (ii) To insure that copayments are not a barrier to the utilization of health services or enrollment in the HMO, an HMO may not impose copayment charges on any subscriber (or enrollees covered by the subscriber's contract with the HMO) in any calendar year, when the copayments made by the subscriber (or enrollees) in that calendar year total 200 percent of the total annual premium cost which that subscriber (or enrollees) would be required to pay if he (or they) were enrolled under an option with no copayments. This limitation applies only if the subscriber (or enrollees) demonstrates that copayments in that amount have been paid in that year.
- (b) *Community rating system.* Under a community rating system, rates of payment

for health services may be determined on a per person or per family basis, as described in paragraph (b)(1) of this section or on a per group basis as described in paragraph (b)(2) of this section. An HMO may fix its rates of payment under the system described in paragraph (b)(1) or (b)(2) of this section or under both such systems, but an HMO may use only one such system for fixing its rates of payment for any one group.

- (1) A system of fixing rates of payment for health services may provide that the rates will be fixed on a per person or per family basis and may vary with the number of persons in a family. Except as otherwise authorized in this paragraph, these rates must be equivalent for all individuals and for all families of similar composition. Rates of payment may be based on either a schedule of rates charged to each subscriber group or on a per-enrollee-per-month (or per-subscriber-per-month) revenue requirement for the HMO. In the former event, rates may vary from group to group if the projected total revenue from each group is substantially equivalent to the revenue that would be derived if the schedule of rates were uniform for all groups. In the latter event, the payments from each group of subscribers must be calculated to yield revenues substantially equivalent to the product of the total number of enrollees (or subscribers) expected to be enrolled from the group and the per-enrollee-per-month (or per-subscriber-per-month) revenue requirement for the HMO. Under the system described in this paragraph, rates of payment may not vary because of actual or anticipated utilization of services by individuals associated with any specific group of subscribers. These provisions do not preclude changes in the rates of payment that are established for new enrollments or re-enrollments and that do not apply to existing contracts until the renewal of these contracts.
- (2) A system of fixing rates of payment for health services may provide that the rates will be fixed for individuals and families by groups. Except as otherwise authorized in this paragraph, such rates must be equivalent for

all individuals in the same group and for all families of similar composition in the same group. If an HMO is to fix rates of payment for individuals and families by groups, it must:

(i) Classify all of the enrollees of the organization into classes based on factors that the HMO determines predict the differences in the use of health services by the individuals or families in each class and which have not been disapproved by CMS,

(ii) Determine its revenue requirements for providing services to the enrollees of each class established under paragraph (b)(2)(i) of this section, and

(iii) Fix the rates of payment for the individuals and families of a group on the basis of a composite of the organization's revenue requirements determined under paragraph (b)(2)(ii) of this section for providing services to them as members of the classes established under paragraph (b)(2)(i) of this section. CMS will review the factors used by each HMO to establish classes under paragraph (b)(2)(i) of this section. If CMS determines that any such factor may not reasonably be used to predict the use of the health services by individuals and families, CMS will disapprove the factor for that purpose.

(3)(i) Nominal differentials in rates may be established to reflect differences in marketing costs and the different administrative costs of collecting payments from the following categories of potential subscribers:

(A) Individual (non-group) subscribers (including their families).

(B) Small groups of subscribers (100 subscribers or fewer).

(C) Large groups of subscribers (over 100 subscribers).

(ii) Differentials in rates may be established for subscribers enrolled in an HMO: (A) Under a contract with a governmental authority under section 1079 ("Contracts for Medical Care for Spouses and Children: Plans") or section 1086 ("Contracts for Health Benefits for Certain Members, Former

Members and their Dependents") of title 10 ("Armed Forces"), United States Code; or (B) under any other governmental program (other than the health benefits program authorized by chapter 89

("Health Insurance") of title 5

("Government Organization and Employees"), United States Code; or (C)

under any health benefits program for employees of States, political subdivisions of states, and other public entities.

(4) An HMO may establish a separate community rate for separate regional components of the organization upon satisfactory demonstration to CMS of the following:

(i) Each regional component is geographically distinct and separate from any other regional component; and

(ii) Each regional component provides substantially the full range of basic health services to its enrollees, without extensive referral between components of the organization for these services, and without substantial utilization by any two components of the same health care facilities. The separate community rate for each regional component of the HMO must be based on the different costs of providing health services in the respective regions.

(c) *Exceptions to community rating requirement.*

(1) In the case of an HMO that provided comprehensive health services on a prepaid basis before it became a qualified HMO, the requirement of community rating shall not apply to the HMO during the forty-eight month period beginning with the month following the month in which it became a qualified HMO.

(2) The requirement of community rating does not apply to the basic health services payment for basic health services provided an enrollee who is a full-time student at an accredited institution of higher education.

(d) *Late payment penalty.* HMOs may charge a late payment penalty on accounts receivable that are in arrears.

(e) *Review procedures for evaluating the community rating by class system under paragraph (b)(2).*¹⁴ An HMO may establish a community rating system under paragraph (b)(2) of this section or revised factors used to establish classes after it receives written approval of the factors from CMS. CMS will give approval if it concludes that the factors can reasonably be used to predict the use of health services by individuals and families.

(1) An HMO must make a written request to CMS, listing the factors to be used in the community rating by class system under paragraph (b)(2) of this section.

(2) CMS will notify each HMO within 30 days of receipt of the request and application of one of the following:

(i) The application is approved;

(ii) Additional information or data are required and CMS will notify the HMO of its decision within 30 days from the date of receipt of this information or data; or

(iii) CMS needs additional time to review the written request and the HMO will be notified of CMS's decision within 90 days.

(Approved by the Office of Management and Budget under control number 0915-0051)

(Sec. 215 of the Public Health Service Act, as amended, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); secs. 1301-1318, as amended, Pub. L. 97-35, 95 Stat. 572-578 (42 U.S.C. 300e-300e-17) [45 FR 72528, Oct. 31, 1980, as amended at 47 FR 19339, May 5, 1982; 50 FR 6175, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 56 FR 8853, Mar. 1, 1991; 58 FR 38082, 38083, July 15, 1993]

§ 417.105 Payment for supplemental health services.

(a) An HMO may require supplemental health services payments, in addition to the basic health services payments, for the provision of

each health service included in the supplemental health services set forth in § 417.102 for which subscribers have contracted, or it may include supplemental health services in the basic health services provided its enrollees for a basic health services payment.

(b) Supplemental health services payments may be made in any agreed upon manner, such as prepayment or fee-for-service. Supplemental health services payments that are fixed on a prepayment basis, however, must be fixed under a community rating system, unless the supplemental health services payment is for a supplemental health service provided an enrollee who is a full-time student at an accredited institution of higher education. In the case of an HMO that provided comprehensive health services on a prepaid basis before it became a qualified HMO, the community rating requirement shall not apply to that HMO during the forty-eight month period beginning with the month following the month in which it became a qualified HMO.

(Sec. 215 of the Public Health Service Act, as amended, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); secs. 1301-1318, as amended, Pub. L. 97-35, 95 Stat. 572-578 (42 U.S.C. 300e-300e-17) [45 FR 72528, Oct. 31, 1980, as amended at 50 FR 6175, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 58 FR 38082, 38083, July 15, 1993]

Subpart J—Qualifying Conditions for Medicare Contracts

SOURCE: 50 FR 1346, Jan. 10, 1985, unless otherwise noted.

§ 417.400 Basis and scope.

(a) *Statutory basis.* The regulations in this subpart implement section 1876 of the Act, which authorizes Medicare payment to HMOs and CMPs that contract with CMS to furnish covered services to Medicare beneficiaries.

(b) *Scope.* (1) This subpart sets forth the requirements an HMO or CMP must meet in order to enter into a contract with CMS under

¹⁴ Further information entitled "Guidelines for Rating by Class" may be obtained from the Office of Prepaid Health Care, Division of Qualification Analysis, HHS Cohen Bldg., room 4360, 330 Independence Ave. SW., Washington, DC 20201.

section 1876 of the Act. It also specifies the procedures that CMS follows to evaluate applications and make determinations.

(2) The rules for payment to HMOs and CMPs are set forth in subparts N, O, and P of this part.

(3) The rules for HCPP participation in Medicare under section 1833(a)(1)(A) of the Act are set forth in subpart U of this part.

[60 FR 45675, Sept. 1, 1995]

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§ 417.414 Qualifying condition: Range of services.

(a) *Condition.* The HMO or CMP must demonstrate that it is capable of delivering to Medicare enrollees the range of services required in accordance with this section.

(b) *Standard: Range of services furnished by eligible HMOs or CMPs.*

(1) *Basic requirement.* Except as specified in paragraph (b)(3) of this section, an HMO or CMP must furnish to its Medicare enrollees (directly or through arrangements with others) all the Medicare services to which those enrollees are entitled to the extent that they are available to Medicare beneficiaries who reside in the HMO's or CMP's geographic area but are not enrolled in the HMO or CMP.

(2) *Criteria for availability.* The services are considered available if—

(i) The sources are located within the HMO's or CMP's geographic area; or

(ii) It is common practice to refer patients to sources outside that geographic area.

(3) *Exception for hospice care.* An HMO or CMP is not required to furnish hospice care as described in part 418 of this chapter.

However, HMOs or CMPs must inform their Medicare enrollees about the availability of hospice care if—

(i) A hospice participating in Medicare is located within the HMO's or CMP's geographic area; or

(ii) It is common practice to refer patients to hospices outside the geographic area.

(c) *Standard: Financial responsibility for services furnished outside the HMO or CMP.*

(1) An HMO or CMP must assume financial

responsibility and provide reasonable reimbursement for emergency services and urgently needed services (as defined in § 417.401) that are obtained by its Medicare enrollees from providers and suppliers outside the HMO or CMP even in the absence of the HMO's or CMP's prior approval.

(2) An HMO or CMP must assume financial responsibility for services that the Medicare enrollee attempted to obtain from the HMO or CMP, but that the HMO or CMP failed to furnish or unreasonably denied, and that are found, upon appeal by the enrollee under subpart Q of this part, to be services that the enrollee was entitled to have furnished to him or her by the HMO or CMP.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38078, July 15, 1993; 60 FR 45677, Sept. 1, 1995]

§ 417.416 Qualifying condition: Furnishing of services.

(a) *Condition.* The HMO or CMP must furnish the required services to its Medicare enrollees through providers and suppliers that meet applicable Medicare statutory definitions and implementing regulations. The HMO or CMP must also ensure that the required services, additional services, and any other supplemental services for which the Medicare enrollee has contracted are available and accessible and are furnished in a manner that ensures continuity.

(b) *Standard: Conformance with conditions of participation, conditions for coverage, and conditions for certification.* (1)

Hospitals, SNFs, HHAs, CORFs, and providers of outpatient physical therapy or speech-language pathology services must meet the applicable conditions of participation in Medicare, as set forth elsewhere in this chapter.

(2) Suppliers must meet the conditions for coverage or conditions for certification of their services, as set forth elsewhere in this chapter.

(3) If more than one type of practitioner is qualified to furnish a particular service, the

HMO or CMP may select the type of practitioner to be used.

(c) *Standard: Physician supervision.* The HMO or CMP must provide for supervision by a physician of other health care professionals who are directly involved in the provision of health care as generally authorized under section 1861 of the Act. Except as specified in paragraph (d) of this section, with respect to medical services furnished in an HMO's or CMP's clinic or the office of a physician with whom the HMO or CMP has a service agreement, the HMO or CMP must ensure that—

(1) Services furnished by paramedical, ancillary, and other nonphysician personnel are furnished under the direct supervision of a physician;

(2) A physician is present to perform medical (as opposed to administrative) services whenever the clinics or offices are open; and

(3) Each patient is under the care of a physician.

(d) *Exceptions to physician supervision requirement.* The following services may be furnished without the direct personal supervision of a physician:

(1) Services of physician assistants and nurse practitioners (as defined in § 491.2 of this chapter), and the services and supplies incident to their services. The conditions for payment, as set forth in §§ 405.2414 and 405.2415 of this chapter for services furnished by rural health clinics and Federally qualified health centers, respectively, also apply when those services are furnished by an HMO or CMP.

(2) When furnished by an HMO or CMP, services of clinical psychologists who meet the qualifications specified in § 410.71(d) of this chapter, and the services and supplies incident to their professional services.

(3) When an HMO or CMP contracts on—

(i) A risk basis, the services of a **clinical social worker** (as defined at § 410.73 of this chapter) and the services and supplies incident to their professional services; or

(ii) A cost basis, the services of a **clinical social worker** (as defined in § 410.73 of this chapter). Services incident to the professional services of a **clinical social worker** furnished by an HMO or CMP contracting on a cost basis are not covered by Medicare and payment will not be made for these services.

(e) *Standard: Accessibility and continuity.*

(1) The HMO or CMP must ensure that the required services and any other services for which Medicare enrollees have contracted are accessible, with reasonable promptness, to the enrollees with respect to geographic location, hours of operation, and provision of after hours service. Medically necessary emergency services must be available twenty-four hours a day, seven days a week.

(2) The HMO or CMP must maintain a health (including medical) recordkeeping system through which pertinent information relating to the health care of its Medicare enrollees is accumulated and is readily available to appropriate professionals.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45677, Sept. 1, 1995; 63 FR 20130, Apr. 23, 1998]

HOME HEALTH AGENCY SERVICES – MEDICAL SOCIAL SERVICES/SOCIAL WORKER

Home health agency services, covered under Medicare Part A and Part B, provides for reimbursement of medical social services when prescribed by a physician.

The regulations (42 CFR 484.34) describe the medical social services component as therapeutic services that must be provided by a qualified social worker or a qualified social work assistant under the supervision of a qualified social worker. According to the regulations, the role of the social worker is the following: (1) to assist the physician and other health professionals in understanding the social and emotional factors related to patients' health problems, (2) to participate in the development of a treatment plan, (3) to prepare clinical and progress notes, (4) to work with a patient's family, (5) to assess and ensure use of appropriate community resources, and (6) to assist in discharge planning and in-service training programs. Although the regulatory provisions for medical social services are specific, the use of such services rests on a physician prescribing medical social services as part of the treatment plan. Without such direction, medical social services are not reimbursable. The Center for Medicare and Medicaid Services (CMS) *Medicare Benefit Policy Manual (Chapter 7)* and Home Health Agency Manual (Chapter 2) offer additional guidance on the medical social services component, including the basis for provider reimbursement and the various functions performed by a social worker in a home health agency setting.¹⁵

As defined in the current regulations (42 CFR 484.4), a social worker must have a master's degree from a school of social work accredited by the Council on Social Work Education and one year of social work experience in a health care setting. A social work assistant must have a baccalaureate degree in social work, sociology, or other field related to social work and at least one year of social work experience in a health care setting. Alternatively, a social work assistant may have two years of appropriate experience as a social work assistant and have achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service. (See the regulations [42 CFR 484.4] for limitations on the application of such an examination.)

¹⁵ Blanchard, L., Gil, G., & Williams, E. (1991, April). *Guidelines and documentation requirements for social workers in home health care*. Silver Spring, MD: National Association of Social Workers.

SOCIAL SECURITY ACT § 1814

42USC1395f

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part A--Hospital Insurance Benefits for Aged and Disabled

Sec. 1395f. Conditions of and limitations on payment for services

(a) Requirement of requests and certifications

Except as provided in subsections (d) and (g) of this section and in section 1395mm of this title, payment for services furnished an individual may be made only to providers of services which are eligible therefor under section 1395cc of this title and only if--

(1) written request, signed by such individual, except in cases in which the Secretary finds it impracticable for the individual to do so, is filed for such payment in such form, in such manner, and by such person or persons as the Secretary may by regulation prescribe, no later than the close of the period of 3 calendar years following the year in which such services are furnished (deeming any services furnished in the last 3 calendar months of any calendar year to have been furnished in the succeeding calendar year) except that where the Secretary deems that efficient administration so requires, such period may be reduced to not less than 1 calendar year;

(2) a physician, or, in the case of services described in subparagraph (B), a physician, or a nurse practitioner or clinical nurse specialist who does not have a direct or indirect employment relationship with the facility but is working in collaboration with a physician, certifies (and recertifies, where such services are furnished over a period of time, in such cases, with such frequency, and accompanied by such supporting material, appropriate to the case involved, as may be provided by regulations, except that the first of such recertifications shall be required in each case of inpatient hospital services not later than the 20th day of such period) that--

(A) in the case of inpatient psychiatric hospital services, such services are or were required to be given on an inpatient basis, by or under the supervision of a physician, for the psychiatric treatment of an individual; and (i) such treatment can or could reasonably be expected to improve the condition for which such treatment is or was necessary or (ii) inpatient diagnostic study is or was medically required and such services are or were necessary for such purposes;

(B) in the case of post-hospital extended care services, such services are or were required to be given because the individual needs or needed on a daily basis skilled nursing care (provided directly by or requiring the supervision of skilled nursing personnel) or other skilled rehabilitation services, which as a practical matter can only be provided in a skilled nursing facility on an inpatient basis, for any of the conditions with respect to which he was receiving inpatient hospital services (or services which would constitute inpatient hospital services if the institution met the requirements of paragraphs (6) and (9) of section 1395x(e) of this title) prior to transfer to the skilled nursing facility or for a condition requiring such extended care services which arose after such transfer and while he was still in the facility for treatment of the condition or conditions for which he was receiving such inpatient hospital services;

(C) in the case of home health services, such services are or were required because the individual is or was confined to his home (except when receiving items and services referred to in section 1395x(m)(7) of this title) and needs or needed skilled nursing care (other than solely venipuncture for the purpose of obtaining a blood sample) on an intermittent basis or physical or speech therapy or, in the case of an individual who has been furnished home health services

based on such a need and who no longer has such a need for such care or therapy, continues or continued to need occupational therapy; a plan for furnishing such services to such individual has been established and is periodically reviewed by a physician; and such services are or were furnished while the individual was under the care of a physician; or

(D) in the case of inpatient hospital services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, the individual, because of his underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services;

SOCIAL SECURITY ACT § 1861

42USC1395x

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part D--Miscellaneous Provisions

Sec. 1395x. Definitions

For purposes of this subchapter--

...

(m) Home health services

The term ``home health services" means the following items and services furnished to an individual, who is under the care of a physician, by a home health agency or by others under arrangements with them made by such agency, under a plan (for furnishing such items and services to such individual) established and periodically reviewed by a physician, which items and services are, except as provided in paragraph

(7), provided on a visiting basis in a place of residence used as such individual's home--

(1) part-time or intermittent nursing care provided by or under the supervision of a registered professional nurse;

(2) physical or occupational therapy or speech-language pathology services;

(3) **medical social services under the direction of a physician;**

(4) to the extent permitted in regulations, part-time or intermittent services of a home health aide who has successfully completed a training program approved by the Secretary;

(5) medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care, and a covered osteoporosis drug (as defined in subsection (kk) of this section), but excluding other drugs and biologicals) and durable medical equipment while under such a plan;

(6) in the case of a home health agency which is affiliated or under common control with a hospital, medical services provided by an intern or resident-in-training of such hospital, under a teaching program of such hospital approved as provided in the last sentence of subsection (b) of this section; and

(7) any of the foregoing items and services which are provided on an outpatient basis, under arrangements made by the home health agency, at a hospital or skilled nursing facility, or at a rehabilitation center which meets such standards as may be prescribed in regulations, and--

(A) the furnishing of which involves the use of equipment of such a nature that the items and services cannot readily be made available to the individual in such place of residence, or

(B) which are furnished at such facility while he is there to receive any such item or service described in clause (A),

but not including transportation of the individual in connection with any such item or service;

excluding, however, any item or service if it would not be included under subsection (b) of this section if furnished to an inpatient of a hospital. For purposes of paragraphs (1) and (4), the term ``part-time or intermittent services" means skilled nursing and home health aide services furnished any number of days per week as long as they are furnished (combined) less than 8 hours each day

and 28 or fewer hours each week (or, subject to review on a case-by-case basis as to the need for care, less than 8 hours each day and 35 or fewer hours per week). For purposes of sections 1395f(a)(2)(C) and 1395n(a)(2)(A) of this title, ``intermittent" means skilled nursing care that is either provided or needed on fewer than 7 days each week, or less than 8 hours of each day for periods of 21 days or less (with extensions in exceptional circumstances when the need for additional care is finite and predictable).

...

(o) Home health agency

The term ``home health agency" means a public agency or private organization, or a subdivision of such an agency or organization, which--

(1) is primarily engaged in providing skilled nursing services and other therapeutic services;

(2) has policies, established by a group of professional personnel (associated with the agency or organization), including one or more physicians and one or more registered professional nurses, to govern the services (referred to in paragraph (1)) which it provides, and provides for supervision of such services by a physician or registered professional nurse;

(3) maintains clinical records on all patients;

(4) in the case of an agency or organization in any State in which State or applicable local law provides for the licensing of agencies or organizations of this nature, (A) is licensed pursuant to such law, or (B) is approved, by the agency of such State or locality responsible for licensing agencies or organizations of this nature, as meeting the standards established for such licensing;

(5) has in effect an overall plan and budget that meets the requirements of subsection (z) of this section;

(6) meets the conditions of participation specified in section 1395bbb(a) of this title and such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such agency or organization;

(7) provides the Secretary with a surety bond--

(A) effective for a period of 4 years (as specified by the Secretary) or in the case of a change in the ownership or control of the agency (as determined by the Secretary) during or after such 4-year period, an additional period of time that the Secretary determines appropriate, such additional period not to exceed 4 years from the date of such change in ownership or control;

(B) in a form specified by the Secretary; and

(C) for a year in the period described in subparagraph (A) in an amount that is equal to the lesser of \$50,000 or 10 percent of the aggregate amount of payments to the agency under this subchapter and subchapter XIX of this chapter for that year, as estimated by the Secretary; and

(8) meets such additional requirements (including conditions relating to bonding or establishing of escrow accounts as the Secretary finds necessary for the financial security of the program) as the Secretary finds necessary for the effective and efficient operation of the program;

except that for purposes of part A of this subchapter such term shall not include any agency or organization which is primarily for the care and treatment of mental diseases. The Secretary may waive the requirement of a surety bond under paragraph (7) in the case of an agency or organization that provides a comparable surety bond under State law.

SOCIAL SECURITY ACT § 1891

42USC1395bbb

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part D--Miscellaneous Provisions

Sec. 1395bbb. Conditions of participation for home health agencies; home health quality

(a) Conditions of participation; protection of individual rights; notification of State entities; use of home health aides; medical equipment; individual's plan of care; compliance with Federal, State, and local laws and regulations

The conditions of participation that a home health agency is required to meet under this subsection are as follows:

(1) The agency protects and promotes the rights of each individual under its care, including each of the following rights:

(A) The right to be fully informed in advance about the care and treatment to be provided by the agency, to be fully informed in advance of any changes in the care or treatment to be provided by the agency that may affect the individual's well-being, and (except with respect to an individual adjudged incompetent) to participate in planning care and treatment or changes in care or treatment.

(B) The right to voice grievances with respect to treatment or care that is (or fails to be) furnished without discrimination or reprisal for voicing grievances.

(C) The right to confidentiality of the clinical records described in section 1395x(o)(3) of this title.

(D) The right to have one's property treated with respect.

(E) The right to be fully informed orally and in writing (in advance of coming under the care of the agency) of--

(i) all items and services furnished by (or under arrangements with) the agency for which payment may be made under this subchapter,

(ii) the coverage available for such items and services under this subchapter, subchapter XIX of this chapter, and any other Federal program of which the agency is reasonably aware,

(iii) any charges for items and services not covered under this subchapter and any charges the individual may have to pay with respect to items and services furnished by (or under arrangements with) the agency, and

(iv) any changes in the charges or items and services described in clause (i), (ii), or (iii).

(F) The right to be fully informed in writing (in advance of coming under the care of the agency) of the individual's rights and obligations under this subchapter.

(G) The right to be informed of the availability of the State home health agency hot-line established under section 1395aa(a) of this title.

(2) The agency notifies the State entity responsible for the licensing or certification of the agency of a change in--

(A) the persons with an ownership or control interest (as defined in section 1320a-3(a)(3) of this title) in the agency,

(B) the persons who are officers, directors, agents, or managing employees (as defined in section 1320a-5(b) of this title) of the agency, and

(C) the corporation, association, or other company responsible for the management of the agency.

Such notice shall be given at the time of the change and shall include the identity of each new person or company described in the previous sentence.

(3)(A) The agency must not use as a home health aide (on a full-time, temporary, per diem, or other basis), any individual to provide items or services described in section 1395x(m) of this title on or after January 1, 1990, unless the individual--

(i) has completed a training and competency evaluation program, or a competency evaluation program, that meets the minimum standards established by the Secretary under subparagraph (D), and

(ii) is competent to provide such items and services.

For purposes of clause (i), an individual is not considered to have completed a training and competency evaluation program, or a competency evaluation program if, since the individual's most recent completion of such a program, there has been a continuous period of 24 consecutive months during none of which the individual provided items and services described in section 1395x(m) of this title for compensation.

(B)(i) The agency must provide, with respect to individuals used as a home health aide by the agency as of July 1, 1989, for a competency evaluation program (as described in subparagraph (A)(i)) and such preparation as may be necessary for the individual to complete such a program by January 1, 1990.

(ii) The agency must provide such regular performance review and regular in-service education as assures that individuals used to provide items and services described in section 1395x(m) of this title are competent to provide those items and services.

(C) The agency must not permit an individual, other than in a training and competency - evaluation program that meets the minimum standards established by the Secretary under - subparagraph (D), to provide items or services of a type for which the individual has not - demonstrated competency. -

(D)(i) The Secretary shall establish minimum standards for the programs described in - subparagraph (A) by not later than October 1, 1988. -

(ii) Such standards shall include the content of the curriculum, minimum hours of training, - qualification of instructors, and procedures for determination of competency. -

(iii) Such standards may permit approval of programs offered by or in home health agencies, as well as outside agencies (including employee organizations), and of programs in effect on December 22, 1987; except that they may not provide for the approval of a program offered by or in a home health agency which, within the previous 2 years--

(I) has been determined to be out of compliance with subparagraph (A), (B), or (C);

(II) has been subject to an extended (or partial extended) survey under subsection (c)(2)(D) of this section;

(III) has been assessed a civil money penalty described in subsection (f)(2)(A)(i) of this - section of not less than \$5,000; or -

(IV) has been subject to the remedies described in subsection (e)(1) of this section or in clauses (ii) or (iii) of subsection (f)(2)(A) of this section.

(iv) Such standards shall permit a determination that an individual who has completed (before July 1, 1989) a training and competency evaluation program or a competency evaluation program shall be deemed for purposes of subparagraph (A) to have completed a program that is approved by the Secretary under the standards established under this subparagraph if the Secretary determines that, at the time the program was offered, the program met such standards.

(E) In this paragraph, the term ``home health aide" means any individual who provides the items and services described in section 1395x(m) of this title, but does not include an individual--

(i) who is a licensed health professional (as defined in subparagraph (F)), or

(ii) who volunteers to provide such services without monetary compensation.

(F) In this paragraph, the term ``licensed health professional" means a physician, physician assistant, nurse practitioner, physical, speech, or occupational therapist, physical or occupational therapy assistant, registered professional nurse, licensed practical nurse, **or licensed or certified social worker.**

PART 484--HOME HEALTH SERVICES

Subpart A—General Provisions

§ 484.1 Basis and scope.

(a) *Basis and scope.* This part is based on the indicated provisions of the following sections of the Act: (1) Sections 1861(o) and 1891 establish the conditions that an HHA must meet in order to participate in Medicare.

(2) Section 1861(z) specifies the Institutional planning standards that HHAs must meet.

(3) Section 1895 provides for the establishment of a prospective payment system for home health services covered under Medicare.

(b) This part also sets forth additional requirements that are considered necessary to ensure the health and safety of patients. [60 FR 50443, Sept. 29, 1995, as amended at 65 FR 41211, July 3, 2000]

§ 484.2 Definitions.

As used in this part, unless the context indicates otherwise—*Bylaws or equivalent* means a set of rules adopted by an HHA for governing the agency's operation.

Branch office means a location or site from which a home health agency provides services within a portion of the total geographic area served by the parent agency. The branch office is part of the home health agency and is located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the branch independently to meet the conditions of participation as a home health agency.

Clinical note means a notation of a contact with a patient that is written and dated by a member of the health team, and that describes signs and symptoms, treatment and drugs administered and the patient's reaction, and any changes in physical or emotional condition.

HHA stands for home health agency.

Nonprofit agency means an agency exempt from Federal income taxation under section 501 of the Internal Revenue Code of 1954.

Parent home health agency means the agency that develops and maintains administrative controls of subunits and/or branch offices.

Primary home health agency means the agency that is responsible for the services furnished to patients and for implementation of the plan of care.

Progress note means a written notation, dated and signed by a member of the health team, that summarizes facts about care furnished and the patient's response during a given period of time.

Proprietary agency means a private profit-making agency licensed by the State.

Public agency means an agency operated by a State or local government. *Subdivision* means a component of a multi-function health agency, such as the home care department of a hospital or the nursing division of a health department, which independently meets the conditions of participation for HHAs. A subdivision that has subunits or branch offices is considered a parent agency.

Subunit means a semi-autonomous organization that—

- (1) Serves patients in a geographic area different from that of the parent agency; and
- (2) Must independently meet the conditions of participation for HHAs because it is too far from the parent agency to share administration, supervision, and services on a daily basis.

Summary report means the compilation of the pertinent factors of a patient's clinical notes and progress notes that is submitted to the patient's physician.

Supervision means authoritative procedural guidance by a qualified person for the accomplishment of a function or activity.

Unless otherwise specified in this part, the supervisor must be on the premises to supervise an individual who does not meet the qualifications specified in § 484.4.

§ 484.4 Personnel qualifications.

Staff required to meet the conditions set forth in this part are staff who meet the qualifications specified in this section.

Administrator, home health agency. A person who:

- (a) Is a licensed physician; or
- (b) Is a registered nurse; or
- (c) Has training and experience in health service administration and at least 1 year of supervisory or administrative experience in home health care or related health programs.

Audiologist. A person who:

- (a) Meets the education and experience requirements for a Certificate of Clinical Competence in audiology granted by the American Speech-Language-Hearing Association; or
- (b) Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

Home health aide. Effective for services furnished after August 14, 1990, a person who has successfully completed a State-established or other training program that meets the requirements of § 484.36(a) and a competency evaluation program or State licensure program that meets the requirements of § 484.36 (b) or (e), or a competency evaluation program or State licensure program that meets the requirements of § 484.36 (b) or (e). An individual is not considered to have completed a training and competency evaluation program, or a competency evaluation program if, since the individual's most recent completion of this program(s), there has been a continuous period of 24 consecutive months during none of which the individual furnished services described in § 409.40 of this chapter for compensation.

Occupational therapist. A person who:

- (a) Is a graduate of an occupational therapy curriculum accredited jointly by the Committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; or
- (b) Is eligible for the National Registration Examination of the American Occupational Therapy Association; or
- (c) Has 2 years of appropriate experience as an occupational therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapist after December 31, 1977.

Occupational therapy assistant. A person who:

- (a) Meets the requirements for certification as an occupational therapy assistant established by the American Occupational Therapy Association; or
- (b) Has 2 years of appropriate experience as an occupational therapy assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapy assistant after December 31, 1977.

Physical therapist. A person who is licensed as a physical therapist by the State in which practicing, and

- (a) Has graduated from a physical therapy curriculum approved by:
 - (1) The American Physical Therapy Association, or

(2) The Committee on Allied Health Education and Accreditation of the American Medical Association, or
 (3) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association; or
 (b) Prior to January 1, 1966,
 (1) Was admitted to membership by the American Physical Therapy Association, or
 (2) Was admitted to registration by the American Registry of Physical Therapist, or
 (3) Has graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education; or
 (c) Has 2 years of appropriate experience as a physical therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking qualification as a physical therapist after December 31, 1977; or
 (d) Was licensed or registered prior to January 1, 1966, and prior to January 1, 1970, had 15 years of full-time experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy; or
 (e) If trained outside the United States,
 (1) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy.
 (2) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy,
Physical therapy assistant. A person who is licensed as a physical therapy assistant, if

applicable, by the State in which practicing, and

(1) Has graduated from a 2-year college-level program approved by the American Physical Therapy Association; or
 (2) Has 2 years of appropriate experience as a physical therapy assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that these determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as a physical therapy assistant after December 31, 1977.

Physician. A doctor of medicine, osteopathy or podiatry legally authorized to practice medicine and surgery by the State in which such function or action is performed.

Practical (vocational) nurse. A person who is licensed as a practical (vocational) nurse by the State in which practicing.

Public health nurse. A registered nurse who has completed a baccalaureate degree program approved by the National League for Nursing for public health nursing preparation or postregistered nurse study that includes content approved by the National League for Nursing for public health nursing preparation.

Registered nurse (RN). A graduate of an approved school of professional nursing, who is licensed as a registered nurse by the State in which practicing.

***Social work assistant.* A person who:**

(1) Has a baccalaureate degree in social work, psychology, sociology, or other field related to social work, and has had at least 1 year of social work experience in a health care setting; or
(2) Has 2 years of appropriate experience as a social work assistant, and has achieved a satisfactory grade on a proficiency examination conducted,

approved, or sponsored by the U.S. Public Health Service, except that these determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as a social work assistant after December 31, 1977.

***Social worker.* A person who has a master's degree from a school of social work accredited by the Council on Social Work Education, and has 1 year of social work experience in a health care setting.**

***Speech-language pathologist.* A person who:**

- (1) Meets the education and experience requirements for a Certificate of Clinical Competence in (speech pathology or audiology) granted by the American Speech-Language-Hearing Association; or
- (2) Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32973, July 18, 1991]

Subpart B—Administration

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§ 484.14 Condition of participation: Organization, services, and administration.

Organization, services furnished, administrative control, and lines of authority for the delegation of responsibility down to the patient care level are clearly set forth in writing and are readily identifiable.

Administrative and supervisory functions are not delegated to another agency or organization and all services not furnished directly, including services provided through subunits are monitored and controlled by the parent agency. If an agency has subunits, appropriate administrative records are maintained for each subunit.

(a) *Standard: Services furnished.* Parttime or intermittent skilled nursing services and at least one other therapeutic service (physical,

speech, or occupational therapy; medical **social services**; or home health aide services) are made available on a visiting basis, in a place of residence used as a patient's home. An HHA must provide at least one of the qualifying services directly through agency employees, but may provide the second qualifying service and additional services under arrangements with another agency or organization.

(b) *Standard: Governing body.* A governing body (or designated persons so functioning) assumes full legal authority and responsibility for the operation of the agency. The governing body appoints a qualified administrator, arranges for professional advice as required under § 484.16, adopts and periodically reviews written bylaws or an acceptable equivalent, and oversees the management and fiscal affairs of the agency.

(c) *Standard: Administrator.* The administrator, who may also be the supervising physician or registered nurse required under paragraph (d) of this section, organizes and directs the agency's ongoing functions; maintains ongoing liaison among the governing body, the group of professional personnel, and the staff; employs qualified personnel and ensures adequate staff education and evaluations; ensures the accuracy of public information materials and activities; and implements an effective budgeting and accounting system. A qualified person is authorized in writing to act in the absence of the administrator.

(d) *Standard: Supervising physician or registered nurse.* The skilled nursing and other therapeutic services furnished are under the supervision and direction of a physician or a registered nurse (who preferably has at least 1 year of nursing experience and is a public health nurse). This person, or similarly qualified alternate, is available at all times during operating hours and participates in all activities

relevant to the professional services furnished, including the development of qualifications and the assignment of personnel.

(e) *Standard: Personnel policies.* Personnel practices and patient care are supported by appropriate, written personnel policies. Personnel records include qualifications and licensure that are kept current.

(f) *Standard: Personnel under hourly or per visit contracts.* If personnel under hourly or per visit contracts are used by the HHA, there is a written contract between those personnel and the agency that specifies the following:

(1) Patients are accepted for care only by the primary HHA.

(2) The services to be furnished.

(3) The necessity to conform to all applicable agency policies, including personnel qualifications.

(4) The responsibility for participating in developing plans of care.

(5) The manner in which services will be controlled, coordinated, and evaluated by the primary HHA.

(6) The procedures for submitting clinical and progress notes, scheduling of visits, periodic patient evaluation.

(7) The procedures for payment for services furnished under the contract.

(g) *Standard: Coordination of patient services.* All personnel furnishing services maintain liaison to ensure that their efforts are coordinated effectively and support the objectives outlined in the plan of care. The clinical record or minutes of case conferences establish that effective interchange, reporting, and coordination of patient care does occur. A written summary report for each patient is sent to the attending physician at least every 60 days.

(h) *Standard: Services under arrangements.* Services furnished under arrangements are subject to a written contract conforming with the requirements specified in paragraph

(f) of this section and with the requirements of section 1861(w) of the Act (42 U.S.C. 1495x(w)).

(i) *Standard: Institutional planning.*

The HHA, under the direction of the governing body, prepares an overall plan and a budget that includes an annual operating budget and capital expenditure plan.

(1) *Annual operating budget.* There is an annual operating budget that includes all anticipated income and expenses related to items that would, under generally accepted accounting principles, be considered income and expense items. However, it is not required that there be prepared, in connection with any budget, an item by item identification of the components of each type of anticipated income or expense.

(2) *Capital expenditure plan.* (i) There is a capital expenditure plan for at least a 3-year period, including the operating budget year. The plan includes and identifies in detail the anticipated sources of financing for, and the objectives of, each anticipated expenditure of more than \$600,000 for items that would under generally accepted accounting principles, be considered capital items. In determining if a single capital expenditure exceeds \$600,000, the cost of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition, improvement, modernization, expansion, or replacement of land, plant, building, and equipment are included. Expenditures directly or indirectly related to capital expenditures, such as grading, paving, broker commissions, taxes assessed during the construction period, and costs involved in demolishing or razing structures on land are also included.

Transactions that are separated in time, but are components of an overall plan or patient care objective, are viewed in their entirety without regard to their timing. Other costs related to capital expenditures include title

fees, permit and license fees, broker commissions, architect, legal, accounting, and appraisal fees; interest, finance, or carrying charges on bonds, notes and other costs incurred for borrowing funds.

(ii) If the anticipated source of financing is, in any part, the anticipated payment from title V (Maternal and Child Health and Crippled Children's Services) or title XVIII (Medicare) or title XIX (Medicaid) of the Social Security Act, the plan specifies the following:

(A) Whether the proposed capital expenditure is required to conform, or is likely to be required to conform, to current standards, criteria, or plans developed in accordance with the Public Health Service Act or the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963.

(B) Whether a capital expenditure proposal has been submitted to the designated planning agency for approval in accordance with section 1122 of the Act (42 U.S.C. 1320a-1) and implementing regulations.

(C) Whether the designated planning agency has approved or disapproved the proposed capital expenditure if it was presented to that agency.

(3) *Preparation of plan and budget.* The overall plan and budget is prepared under the direction of the governing body of the HHA by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff (if any) of the HHA.

(4) *Annual review of plan and budget.* The overall plan and budget is reviewed and updated at least annually by the committee referred to in paragraph (i)(3) of this section under the direction of the governing body of the HHA.

(j) *Standard: Laboratory services.* (1) If the HHA engages in laboratory testing outside of the context of assisting an individual in

self-administering a test with an appliance that has been cleared for that purpose by the FDA, such testing must be in compliance with all applicable requirements of part 493 of this chapter.

(2) If the HHA chooses to refer specimens for laboratory testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of part 493 of this chapter. [54 FR 33367, August 14, 1989, as amended at 56 FR 32973, July 18, 1991; 56 FR 51334, Oct. 11, 1991; 57 FR 7136, Feb. 28, 1992; 66 FR 32778, June 18, 2001]

§ 484.16 Condition of participation:

Group of professional personnel.

A group of professional personnel, which includes at least one physician and one registered nurse (preferably a public health nurse), and with **appropriate representation from other professional disciplines**, establishes and annually reviews the agency's policies governing scope of services offered, admission and discharge policies, medical supervision and plans of care, emergency care, clinical records, personnel qualifications, and program evaluation. At least one member of the group is neither an owner nor an employee of the agency.

(a) *Standard: Advisory and evaluation function.* The group of professional personnel meets frequently to advise the agency on professional issues, to participate in the evaluation of the agency's program, and to assist the agency in maintaining liaison with other health care providers in the community and in the agency's community information program. The meetings are documented by dated minutes. [54 FR 33367, August 14, 1989, as amended at 56 FR 32974, July 18, 1991]

§ 484.18 Condition of participation:

Acceptance of patients, plan of care, and medical supervision.

Patients are accepted for treatment on the basis of a reasonable expectation that the patient's medical, nursing, and social needs can be met adequately by the agency in the patient's place of residence. Care follows a written plan of care established and periodically reviewed by a doctor of medicine, osteopathy, or podiatric medicine.

(a) *Standard: Plan of care.* The plan of care developed in consultation with the agency staff covers all pertinent diagnoses, including mental status, types of services and equipment required, frequency of visits, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, medications and treatments, any safety measures to protect against injury, instructions for timely discharge or referral, and any other appropriate items. If a physician refers a patient under a plan of care that cannot be completed until after an evaluation visit, the physician is consulted to approve additions or modifications to the original plan. Orders for therapy services include the specific procedures and modalities to be used and the amount, frequency, and duration. The therapist and other agency personnel participate in developing the plan of care.

(b) *Standard: Periodic review of plan of care.* The total plan of care is reviewed by the attending physician and HHA personnel as often as the severity of the patient's condition requires, but at least once every 60 days or more frequently when there is a beneficiary elected transfer; a significant change in condition resulting in a change in the case-mix assignment; or a discharge and return to the same HHA during the 60-day episode. Agency professional staff promptly alert the physician to any changes that suggest a need to alter the plan of care.

(c) *Standard: Conformance with physician orders.* Drugs and treatments are administered by agency staff only as ordered by the physician with the exception of

influenza and pneumococcal polysaccharide vaccines, which may be administered per agency policy developed in consultation with a physician, and after an assessment for contraindications. Verbal orders are put in writing and signed and dated with the date of receipt by the registered nurse or qualified therapist (as defined in § 484.4 of this chapter) responsible for furnishing or supervising the ordered services. Verbal orders are only accepted by personnel authorized to do so by applicable State and Federal laws and regulations as well as by the HHA's internal policies.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32974, July 18, 1991; 64 FR 3784, Jan. 25, 1999; 65 FR 41211, July 3, 2000; 67 FR 61814, Oct. 2, 2002]

**§ 484.20 Condition of participation:
Reporting OASIS information.**

HHAs must electronically report all OASIS data collected in accordance with § 484.55.

(a) *Standard: Encoding OASIS data.*

The HHA must encode and be capable of transmitting OASIS data for each agency patient within 7 days of completing an OASIS data set.

(b) *Standard: Accuracy of encoded OASIS data.* The encoded OASIS data must accurately reflect the patient's status at the time of assessment.

(c) *Standard: Transmittal of OASIS data.* The HHA must—

- (1) Electronically transmit accurate, completed, encoded and locked OASIS data for each patient to the State agency or CMS OASIS contractor at least monthly;
- (2) For all assessments completed in the previous month, transmit OASIS data in a format that meets the requirements of paragraph (d) of this section;
- (3) Successfully transmit test data to the State agency or CMS OASIS contractor beginning March 26, 1999, and no later than April 26, 1999; and

(4) Transmit data using electronic communications software that provides a direct telephone connection from the HHA to the State agency or CMS OASIS contractor.

(d) *Standard: Data Format.* The HHA must encode and transmit data using the software available from CMS or software that conforms to CMS standard electronic record layout, edit specifications, and data dictionary, and that includes the required OASIS data set.

[64 FR 3763, Jan. 25, 1999]

Subpart C—Furnishing of Services

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§ 484.34 Condition of participation: Medical social services.

If the agency furnishes **medical social services**, those services are given by a **qualified social worker or by a qualified social work assistant under the supervision of a qualified social worker**, and in accordance with the plan of care. The **social worker** assists the physician and other team members in understanding the significant social and emotional factors related to the health problems, participates in the development of the plan of care, prepares clinical and progress notes, works with the family, uses appropriate community resources, participates in discharge planning and in-service programs, and acts as a consultant to other agency personnel.

PART 409--HOSPITAL INSURANCE BENEFITS

Subpart E—Home Health Services Under Hospital Insurance

§ 409.40 Basis, purpose, and scope.

This subpart implements sections 1814(a)(2)(C), 1835(a)(2)(A), and 1861(m) of the Act with respect to the requirements that must be met for Medicare payment to be made for home health services furnished to eligible beneficiaries.

[59 FR 65493, Dec. 20, 1994]

....

§ 409.45 Dependent services requirements.

(a) *General.* Services discussed in paragraphs (b) through (g) of this section may be covered only if the beneficiary needs skilled nursing care on an intermittent basis, as described in § 409.44(b); physical therapy or speech- language pathology services as described in § 409.44(c); or has a continuing need for occupational therapy services as described in § 409.44(c) if the beneficiary's eligibility for home health services has been established by virtue of a prior need for intermittent skilled nursing care, speech- language pathology services, or physical

therapy in the current or prior certification period; and otherwise meets the qualifying criteria (confined to the home, under the care of a physician, in need of skilled services, and under a plan of care) specified in § 409.42. Home health coverage is not available for services furnished to a beneficiary who is no longer in need of one of the qualifying skilled services specified in this paragraph. Therefore, dependent services furnished after the final qualifying skilled service are not covered, except when the dependent service was not followed by a qualifying skilled service as a result of the unexpected inpatient admission or death of the beneficiary, or due to some other unanticipated event.

(b) *Home health aide services.* To be covered, home health aide services must meet each of the following requirements: (1) The reason for the visits by the home health aide must be to provide hands-on personal care to the beneficiary or services that are needed to maintain the beneficiary's health or to facilitate treatment of the beneficiary's illness or injury. The

physician's order must indicate the frequency of the home health aide services required by the beneficiary. These services may include but are not limited to:

(i) Personal care services such as bathing, dressing, grooming, caring for hair, nail and oral hygiene that are needed to facilitate treatment or to prevent deterioration of the beneficiary's health, changing the bed linens of an incontinent beneficiary, shaving, deodorant application, skin care with lotions and/or powder, foot care, ear care, feeding, assistance with elimination (including enemas unless the skills of a licensed nurse are required due to the beneficiary's condition, routine catheter care, and routine colostomy care), assistance with ambulation, changing position in bed, and assistance with transfers.

(ii) Simple dressing changes that do not require the skills of a licensed nurse.

(iii) Assistance with medications that are ordinarily self-administered and that do not require the skills of a licensed nurse to be provided safely and effectively.

(iv) Assistance with activities that are directly supportive of skilled therapy services but do not require the skills of a therapist to be safely and effectively performed, such as routine maintenance exercises and repetitive practice of functional communication skills to support speech-language pathology services.

(v) Routine care of prosthetic and orthotic devices.

(2) The services to be provided by the home health aide must be—

(i) Ordered by a physician in the plan of care; and

(ii) Provided by the home health aide on a part-time or intermittent basis.

(3) The services provided by the home health aide must be reasonable and necessary. To be considered reasonable and necessary, the services must—

(i) Meet the requirement for home health aide services in paragraph (b)(1) of this section;

(ii) Be of a type the beneficiary cannot perform for himself or herself; and

(iii) Be of a type that there is no able or willing caregiver to provide, or, if there is a potential caregiver, the beneficiary is unwilling to use the services of that individual. (4) The home health aide also may perform services incidental to a visit that was for the provision of care as described in paragraphs (b)(3)(i) through (iii) of this section. For example, these incidental services may include changing bed linens, personal laundry, or preparing a light meal.

(c) **Medical social services.** Medical social services may be covered if the following requirements are met:

(1) The services are ordered by a physician and included in the plan of care.

(2)(i) The services are necessary to resolve social or emotional problems that are expected to be an impediment to the effective treatment of the beneficiary's medical condition or to his or her rate of recovery.

(ii) If these services are furnished to beneficiary's family member or caregiver, they are furnished on a short-term basis and it can be demonstrated that the service is necessary to resolve a clear and direct impediment to the effective treatment of the beneficiary's medical condition or to his or her rate of recovery.

(3) The frequency and nature of the **medical social services** are reasonable and necessary to the treatment of the beneficiary's condition.

(4) The **medical social services** are **furnished by a qualified social worker or qualified social work assistant under the supervision of a social worker** as defined in § 484.4 of this chapter.

(5) The services needed to resolve the problems that are impeding the beneficiary's recovery **require the skills of a social worker or a social work assistant under the supervision of a social worker** to be performed safely and effectively.

....

[59 FR 65495, Dec. 20, 1994; 60 FR 39122, 39123, Aug. 1, 1995]

Medicare Benefit Policy Manual
CHAPTER 7 - HOME HEALTH SERVICES

20 - Conditions To Be Met for Coverage of Home Health Services

(Rev. 1, 10-01-03)

A3-3116, HHA-203

Medicare covers HHA services when the following criteria are met:

1. The person to whom the services are provided is an eligible Medicare beneficiary;
2. The HHA that is providing the services to the beneficiary has in effect a valid agreement to participate in the Medicare program;
3. The beneficiary qualifies for coverage of home health services as described in §30;
4. The services for which payment is claimed are covered as described in §§40 and 50;
5. Medicare is the appropriate payer; and
6. The services for which payment is claimed are not otherwise excluded from payment.

20.1 - Reasonable and Necessary Services

(Rev. 1, 10-01-03)

A3-3116.1, HHA-203.1

20.1.1 - Background

(Rev. 1, 10-01-03)

A3-3116.1A, HHA-203.1A

In enacting the Medicare program, Congress recognized that the physician would play an important role in determining utilization of services. The law requires that payment can be made only if a physician certifies the need for services and establishes a plan of care.

The Secretary is responsible for ensuring that Medicare covers the claimed services, including determining whether they are "reasonable and necessary."

20.1.2 - Determination of Coverage

(Rev. 1, 10-01-03)

A3-3113.1.B, HHA-203.1.B

The intermediary's decision on whether care is reasonable and necessary is based on information reflected in the home health plan of care, the OASIS as required by 42 CFR 484.55 or a medical record of the individual patient. Medicare does not deny coverage solely on the basis of the reviewer's general inferences about patients with similar diagnoses or on data related to utilization generally, but bases it upon objective clinical evidence regarding the patient's individual need for care.

...

50.3 - Medical Social Services

(Rev. 1, 10-01-03)

A3-3119.3, HHA-206.3

Medical social services that are provided by a qualified medical social worker or a social work assistant under the supervision of a qualified medical social worker may be covered as home health services where the beneficiary meets the qualifying criteria specified in §30, and:

1. The services of these professionals are necessary to resolve social or emotional problems that are or are expected to be an impediment to the effective treatment of the patient's medical condition or rate of recovery; and
2. The plan of care indicates how the services which are required necessitate the skills of a qualified social worker or a social work assistant under the supervision of a qualified medical social worker to be performed safely and effectively.

Where both of these requirements for coverage are met, services of these professionals which may be covered include, but are not limited to:

1. Assessment of the social and emotional factors related to the patient's illness, need for care, response to treatment and adjustment to care;
2. Assessment of the relationship of the patient's medical and nursing requirements to the patient's home situation, financial resources and availability of community resources;
3. Appropriate action to obtain available community resources to assist in resolving the patient's problem (**NOTE:** Medicare does not cover the services of a medical social worker to complete or assist in the completion of an application for Medicaid because Federal regulations require the State to provide assistance in completing the application to anyone who chooses to apply for Medicaid.);
4. Counseling services that are required by the patient; and
5. Medical social services furnished to the patient's family member or caregiver on a short-term basis when the HHA can demonstrate that a brief intervention (that is, two or three visits) by a medical social worker is necessary to remove a clear and direct impediment to the effective treatment of the patient's medical condition or to the patient's rate of recovery. To be considered "clear and direct," the behavior or actions of the family member or caregiver must plainly obstruct, contravene, or prevent the patient's medical treatment or rate of recovery. Medical social services to address general problems that do not clearly and directly impede treatment or recovery as well as long-term social services furnished to family members, such as ongoing alcohol counseling, are not covered.

NOTE: Participating in the development of the plan of care, preparing clinical and progress notes, participating in discharge planning and in-service programs, and acting as a consultant to other agency personnel are appropriate administrative costs to the HHA.

EXAMPLE 1

The physician has ordered a medical social worker assessment of a diabetic patient who has recently become insulin dependent and is not yet stabilized. The nurse, who is providing skilled observation and evaluation to try to restabilize the patient notices during her visits that the supplies left in the home for the patient's use appear to be frequently missing, and the patient is not compliant with the regimen although she refuses to discuss the matter. The assessment by a medical social worker

would be reasonable and necessary to determine if there are underlying social or emotional problems impeding the patient's treatment.

EXAMPLE 2

A physician ordered an assessment by a medical social worker for a multiple sclerosis patient who was unable to move anything but her head and who had an indwelling catheter. The patient had experienced recurring urinary tract infections and multiple infected ulcers. The physician ordered medical social services after the HHA indicated to him that the home was not well cared for, the patient appeared to be neglected much of the time, and the relationship between the patient and family was very poor. The physician and HHA were concerned that social problems created by family caregivers were impeding the treatment of the recurring infections and ulcers. The assessment and follow-up for counseling both the patient and the family by a medical social worker were reasonable and necessary.

EXAMPLE 3

A physician is aware that a patient with atherosclerosis and hypertension is not taking medications as ordered and adhering to dietary restrictions because he is unable to afford the medication and is unable to cook. The physician orders several visits by a medical social worker to assist in resolving these problems. The visits by the medical social worker to review the patient's financial status, discuss options, and make appropriate contacts with social services agencies or other community resources to arrange for medications and meals would be a reasonable and necessary medical social service.

EXAMPLE 4

A physician has ordered counseling by a medical social worker for a patient with cirrhosis of the liver who has recently been discharged from a 28-day inpatient alcohol treatment program to her home which she shares with an alcoholic and neglectful adult child. The physician has ordered counseling several times per week to assist the patient in remaining free of alcohol and in dealing with the adult child. The services of the medical social worker would be covered until the patient's social situation ceased to impact on her recovery and/or treatment.

EXAMPLE 5

A physician has ordered medical social services for a patient who is worried about his financial arrangements and payment for medical care. The services ordered are to arrange Medicaid if possible and resolve unpaid medical bills. There is no evidence that the patient's concerns are adversely impacting recovery or treatment of his illness or injury. Medical social services cannot be covered.

EXAMPLE 6

A physician has ordered medical social services for a patient of extremely limited income who has incurred large unpaid hospital and other medical bills following a significant illness. The patient's recovery is adversely affected because the patient is not maintaining a proper therapeutic diet, and cannot leave the home to acquire the medication necessary to treat their illness. The medical social worker reviews the patient's financial status, arranges meal service to resolve the dietary problem,

arranges for home delivered medications, gathers the information necessary for application to Medicaid to acquire coverage for the medications the patient needs, files the application on behalf of the patient, and follows up repeatedly with the Medicaid State agency.

The medical social services that are necessary to review the financial status of the patient, arrange for meal service and delivery of medications to the home, and arrange for the Medicaid State agency to assist the patient with the application for Medicaid are covered.

The services related to the assistance in filing the application for Medicaid and the follow-up on the application are not covered since they must be provided by the State agency free of charge, and hence the patient has no obligation to pay for such assistance.

EXAMPLE 7

A physician has ordered medical social services for an insulin dependent diabetic whose blood sugar is elevated because she has run out of syringes and missed her insulin dose for two days. Upon making the assessment visit, the medical social worker learns that the patient's daughter, who is also an insulin dependent diabetic, has come to live with the patient because she is out of work. The daughter is now financially dependent on the patient for all of her financial needs and has been using the patient's insulin syringes. The social worker assesses the patient's financial resources and determines that they are adequate to support the patient and meet her own medical needs, but are not sufficient to support the daughter. She also counsels the daughter and helps her access community resources. These visits would be covered, but only to the extent that the services are necessary to prevent interference with the patient's treatment plan.

EXAMPLE 8

A wife is caring for her husband who is an Alzheimer's patient. The nurse learns that the wife has not been giving the patient his medication correctly and seems distracted and forgetful about various aspects of the patient's care. In a conversation with the nurse, the wife relates that she is feeling depressed and overwhelmed by the patient's illness. The nurse contacts the patient's physician who orders a social work evaluation. In her assessment visit, the social worker learns that the patient's wife is so distraught over her situation that she cannot provide adequate care to the patient. While there, the social worker counsels the wife and assists her with referrals to a support group and her private physician for evaluation of her depression. The services would be covered.

EXAMPLE 9

The parent of a dependent disabled child has been discharged from the hospital following a hip replacement. Although arrangements for care of the disabled child during the hospitalization were made, the child has returned to the home. During a visit to the patient, the nurse observes that the patient is transferring the child from bed to a wheelchair. In an effort to avoid impeding the patient's recovery, the nurse contacts the patient's physician to order a visit by a social worker to mobilize family members or otherwise arrange for temporary care of the disabled child. The services would be covered.

Home Health Agency Manual

CHAPTER 2-COVERAGE OF SERVICES

206.3 Medical Social Services.--Medical social services that are provided by a **qualified medical social worker** or a **social work assistant** under the supervision of a qualified medical social worker may be covered as home health services where the patient meets the qualifying criteria specified in §204, and:

- The services of these professionals are necessary to resolve social or emotional problems that are or are expected to be an impediment to the effective treatment of the patient's medical condition or his or her rate of recovery; and
- The plan of care indicates how the services that are required necessitate the skills of a qualified social worker or a social work assistant under the supervision of a qualified medical social worker to be performed safely and effectively.
- Where both of these requirements for coverage are met, services of these professionals that may be covered include, but are not limited to:
- Assessment of the social and emotional factors related to the patient's illness, need for care, response to treatment and adjustment to care;
- Assessment of the relationship of the patient's medical and nursing requirements to the patient's home situation, financial resources and availability of community resources;
- Appropriate action to obtain available community resources to assist in resolving the patient's problem. (Note: Medicare does not cover the services of a medical social worker to complete or assist in the completion of an application for Medicaid because Federal regulations require the State to provide assistance in completing the application to anyone who chooses to apply for Medicaid.);
- Counseling services which are required by the patient; and
- Medical social services furnished to the patient's family member or caregiver on a short-term basis when the HHA can demonstrate that a brief intervention (that is, two or three visits) by a medical social worker is necessary to remove a clear and direct impediment to the effective treatment of the patient's medical condition or to his or her rate of recovery. To be considered "clear and direct," the behavior or actions of the family member or caregiver must plainly obstruct, contravene, or prevent the patient's medical treatment or rate of recovery. Medical social services to address general problems that do not clearly and directly impede treatment or recovery as well as long-term social services furnished to family members, such as ongoing alcohol counseling, are not covered.

NOTE: Participating in the development of the plan of care, preparing clinical and progress notes, participating in discharge planning and inservice programs, and acting as a consultant to other agency personnel are appropriate administrative costs to the HHA.

END-STAGE RENAL DISEASE SERVICES – SOCIAL SERVICES/SOCIAL WORKER

Medicare covers certain individuals for end-stage renal disease (ESRD) services without regard to age or disability status, although under the secondary payer requirement, during an initial coordination period of up to 12 months, Medicare will only cover expenses when it is not reasonable to expect payment from an employer-based plan. After this coordination period, Medicare pays primary benefits in the usual manner.

Medicare defines ESRD in the regulations as "that stage of renal impairment that appears irreversible and permanent and requires a regular course of dialysis or kidney transplantation to maintain life" (Section 405.2102). The regulations describe the objectives of the ESRD program as follows:

- To assist beneficiaries who have been diagnosed as having ESRD to receive the care they need
- To encourage proper distribution and effective utilization of ESRD treatment resources while maintaining or improving the quality of care
- To provide the flexibility necessary for the efficient delivery of appropriate care by physicians and facilities
- To encourage self-dialysis or transplantation for a maximum practical number of patients who are medically, socially, and psychologically suitable candidates for such treatment.

Beneficiaries who have ESRD are covered for all Part A and Part B services, although they are not eligible to join a health maintenance organization or competitive medical plan.

An ESRD facility can be a hospital-based renal transplantation center, a hospital-based renal dialysis center, a renal dialysis facility (a unit approved to furnish dialysis services directly to ESRD patients), a self-dialysis unit, or a special purpose renal dialysis facility.

In the regulations, social services are specifically cited as a minimum service requirement for a participating renal dialysis facility, renal dialysis center, and a renal transplantation center. The regulations describe social services as services provided to the patient and their family to enable the patient to achieve maximum social functioning and adjustment. The regulations, in addition to defining the qualifications of a social worker, address a full range of social work responsibilities, including psychosocial evaluations, participation in the team review of patient progress, provision of casework and group work services to patients and their families, and referral to appropriate community resources.

Qualified social workers are identified in the regulations as part of a team of professionals in ESRD facilities responsible for developing a long-term program and care plan for each individual receiving ESRD services.

In addition to the above regulations, the statute identifies social workers as members on medical review boards for designated ESRD networks. According to the statute and the regulations, a designated ESRD network brings together a range of approved ESRD services to collectively provide the necessary care for ESRD patients in a given geographical area. The medical review board is charged with evaluating the quality and the appropriateness of the care. The law requires that social workers engaged in treatment relating to end-stage renal disease serve as members of a medical review board. Before 1988 the regulations only provided for "qualified individuals" to

serve on the medical review boards. The regulations (see 42 CFR 405.2113) indicate which professionals shall serve and specifically identifies social workers.

For reimbursement, social workers must be licensed in the state in which they are practicing, hold a master's degree from a school accredited by the Council on Social Work Education, and have served for at least two years as a social worker.

SOCIAL SECURITY ACT § 1881

42USC1395rr

TITLE 42--THE PUBLIC HEALTH AND WELFARE

CHAPTER 7--SOCIAL SECURITY

SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED

Part D--Miscellaneous Provisions

Sec. 1395rr. End stage renal disease program

(a) Type, duration, and scope of benefits

The benefits provided by parts A and B of this subchapter shall include benefits for individuals who have been determined to have end stage renal disease as provided in section 426-1 of this title, and benefits for kidney donors as provided in subsection (d) of this section. Notwithstanding any other provision of this subchapter, the type, duration, and scope of the benefit provided by parts A and B of this subchapter with respect to individuals who have been determined to have end stage renal disease and who are entitled to such benefits without regard to section 426-1 of this title shall in no case be less than the type, duration, and scope of the benefits so provided for individuals entitled to such benefits solely by reason of that section.

(b) Payments with respect to services; dialysis; regulations; physicians' services; target reimbursement rates; home dialysis supplies and equipment; self-care home dialysis support services; self-care dialysis units; hepatitis B vaccine

(1) Payments under this subchapter with respect to services, in addition to services for which payment would otherwise be made under this subchapter, furnished to individuals who have been determined to have end stage renal disease shall include (A) payments on behalf of such individuals to providers of services and renal dialysis facilities which meet such requirements as the Secretary shall by regulation prescribe for institutional dialysis services and supplies (including self-dialysis services in a self-care dialysis unit maintained by the provider or facility), transplantation services, self-care home dialysis support services which are furnished by the provider or facility, and routine professional services performed by a physician during a maintenance dialysis episode if payments for his other professional services furnished to an individual who has end stage renal disease are made on the basis specified in paragraph (3)(A) of this subsection, (B) payments to or on behalf of such individuals for home dialysis supplies and equipment, and (C) payments to a supplier of home dialysis supplies and equipment that is not a provider of services, a renal dialysis facility, or a physician for self-administered erythropoietin as described in section 1395x(s)(2)(P) \1\ of this title if the Secretary finds that the patient receiving such drug from such a supplier can safely and effectively administer the drug (in accordance with the applicable methods and standards established by the Secretary pursuant to such section). The requirements prescribed by the Secretary under subparagraph (A) shall include requirements for a minimum utilization rate for transplantations.

...

(9) For purposes of this subchapter, the term ``self-care home dialysis support services'', to the extent permitted in regulation, means--

(A) periodic monitoring of the patient's home adaptation, including visits by qualified provider or facility personnel (as defined in regulations), so long as this is done in accordance with a plan

prepared and periodically reviewed by a professional team (as defined in regulations) including the individual's physician;

(B) installation and maintenance of dialysis equipment;

(C) testing and appropriate treatment of the water; and

(D) such additional supportive services as the Secretary finds appropriate and desirable.

...

(11)(A) Hepatitis B vaccine and its administration, when provided to a patient determined to have end stage renal disease, shall not be included as dialysis services for purposes of payment under any prospective payment amount or comprehensive fee established under this section. Payment for such vaccine and its administration shall be made separately in accordance with section 1395l of this title.

(B) Erythropoietin, when provided to a patient determined to have end stage renal disease, shall not be included as a dialysis service for purposes of payment under any prospective payment amount or comprehensive fee established under this section, and payment for such item shall be made separately--

(i) in the case of erythropoietin provided by a physician, in accordance with section 1395l of this title; and

(ii) in the case of erythropoietin provided by a provider of services, renal dialysis facility, or other supplier of home dialysis supplies and equipment--

(I) for erythropoietin provided during 1994, in an amount equal to \$10 per thousand units (rounded to the nearest 100 units), and

(II) for erythropoietin provided during a subsequent year, in an amount determined to be appropriate by the Secretary, except that such amount may not exceed the amount determined under this clause for the previous year increased by the percentage increase (if any) in the implicit price deflator for gross national product (as published by the Department of Commerce) for the second quarter of the preceding year over the implicit price deflator for the second quarter of the second preceding year.

(C) The amount payable to a supplier of home dialysis supplies and equipment that is not a provider of services, a renal dialysis facility, or a physician for erythropoietin shall be determined in the same manner as the amount payable to a renal dialysis facility for such item.

(c) Renal disease network areas; coordinating councils, executive committees, and medical review boards; national end stage renal disease medical information system; functions of network organizations

(1)(A)(i) For the purpose of assuring effective and efficient administration of the benefits provided under this section, the Secretary shall, in accordance with such criteria as he finds necessary to assure the performance of the responsibilities and functions specified in paragraph (2)--

(I) establish at least 17 end stage renal disease network areas, and

(II) for each such area, designate a network administrative organization which, in accordance with regulations of the Secretary, shall establish (aa) a network council of renal dialysis and transplant facilities located in the area and (bb) a medical review board, which has a membership including at least one patient representative and physicians, nurses, and **social workers** engaged in treatment relating to end stage renal disease.

The Secretary shall publish in the Federal Register a description of the geographic area that he determines, after consultation with appropriate professional and patient organizations, constitutes each network area and the criteria on the basis of which such determination is made.

(ii) (I) In order to determine whether the Secretary should enter into, continue, or terminate an agreement with a network administrative organization designated for an area established under clause (i), the Secretary shall develop and publish in the Federal Register standards, criteria, and procedures to evaluate an applicant organization's capabilities to perform (and, in the case of an organization with which such an agreement is in effect, actual performance of) the responsibilities described in paragraph (2). The Secretary shall evaluate each applicant based on quality and scope of services and may not accord more than 20 percent of the weight of the evaluation to the element of price.

(II) An agreement with a network administrative organization may be terminated by the Secretary only if he finds, after applying such standards and criteria, that the organization has failed to perform its prescribed responsibilities effectively and efficiently. If such an agreement is to be terminated, the Secretary shall select a successor to the agreement on the basis of competitive bidding and in a manner that provides an orderly transition.

(B) At least one patient representative shall serve as a member of each network council and each medical review board.

(C) The Secretary shall, in regulations, prescribe requirements with respect to membership in network organizations by individuals (and the relatives of such individuals) (i) who have an ownership or control interest in a facility or provider which furnishes services referred to in section 1395x(s)(2)(F) of this title, or (ii) who have received remuneration from any such facility or provider in excess of such amounts as constitute reasonable compensation for services (including time and effort relative to the provision of professional medical services) or goods supplied to such facility or provider; and such requirements shall provide for the definition, disclosure, and, to the maximum extent consistent with effective administration, prevention of potential or actual financial or professional conflicts of interest with respect to decisions concerning the appropriateness, nature, or site of patient care.

(2) The network organizations of each network shall be responsible, in addition to such other duties and functions as may be prescribed by the Secretary, for--

(A) encouraging, consistent with sound medical practice, the use of those treatment settings most compatible with the successful rehabilitation of the patient and the participation of patients, providers of services, and renal disease facilities in vocational rehabilitation programs;

(B) developing criteria and standards relating to the quality and appropriateness of patient care and with respect to working with patients, facilities, and providers in encouraging participation in vocational rehabilitation programs; and network goals with respect to the placement of patients in self-care settings and undergoing or preparing for transplantation;

(C) evaluating the procedure by which facilities and providers in the network assess the appropriateness of patients for proposed treatment modalities;

(D) implementing a procedure for evaluating and resolving patient grievances;

(E) conducting on-site reviews of facilities and providers as necessary (as determined by a medical review board or the Secretary), utilizing standards of care established by the network organization to assure proper medical care;

(F) collecting, validating, and analyzing such data as are necessary to prepare the reports required by subparagraph (H) and to assure the maintenance of the registry established under paragraph (7);

(G) identifying facilities and providers that are not cooperating toward meeting network goals and assisting such facilities and providers in developing appropriate plans for correction and reporting to the Secretary on facilities and providers that are not providing appropriate medical care; and

(H) submitting an annual report to the Secretary on July 1 of each year which shall include a full statement of the network's goals, data on the network's performance in meeting its goals (including data on the comparative performance of facilities and providers with respect to the identification and placement of suitable candidates in self-care settings and transplantation and encouraging participation in vocational rehabilitation programs), identification of those facilities that have consistently failed to cooperate with network goals, and recommendations with respect to the need for additional or alternative services or facilities in the network in order to meet the network goals, including self-dialysis training, transplantation, and organ procurement facilities.

(3) Where the Secretary determines, on the basis of the data contained in the network's annual report and such other relevant data as may be available to him, that a facility or provider has consistently failed to cooperate with network plans and goals or to follow the recommendations of the medical review board, he may terminate or withhold certification of such facility or provider (for purposes of payment for services furnished to individuals with end stage renal disease) until he determines that such provider or facility is making reasonable and appropriate efforts to cooperate with the network's plans and goals. If the Secretary determines that the facility's or provider's failure to cooperate with network plans and goals does not jeopardize patient health or safety or justify termination of certification, he may instead, after reasonable notice to the provider or facility and to the public, impose such other sanctions as he determines to be appropriate, which sanctions may include denial of reimbursement with respect to some or all patients admitted to the facility after the date of notice to the facility or provider, and graduated reduction in reimbursement for all patients.

(4) The Secretary shall, in determining whether to certify additional facilities or expansion of existing facilities within a network, take into account the network's goals and performance as reflected in the network's annual report.

(5) The Secretary, after consultation with appropriate professional and planning organizations, shall provide such guidelines with respect to the planning and delivery of renal disease services as are necessary to assist network organizations in their development of their respective networks' goals to promote the optimum use of self-dialysis and transplantation by suitable candidates for such modalities.

(6) It is the intent of the Congress that the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for home dialysis or transplantation should be so treated and that the maximum practical number of patients who are suitable candidates for vocational rehabilitation services be given access to such services and encouraged to return to gainful employment. The Secretary shall consult with appropriate professional and network organizations and consider available evidence relating to developments in research, treatment methods, and technology for home dialysis and transplantation.

...

PART 405--FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Subparts S–T [Reserved]

Subpart U—Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services

AUTHORITY: Secs. 1102, 1138, 1861, 1862(a), 1871, 1874, and 1881 of the Social Security Act (42 U.S.C. 1302, 1320b–8, 1395x, 1395y(a), 1395hh, 1395kk, and 1395rr), unless otherwise noted.

SOURCE: 41 FR 22511, June 3, 1976, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.2100 Scope of subpart.

(a) The regulations in this subpart prescribe the role which End-Stage Renal Disease (ESRD) networks have in the ESRD program, establish the mechanism by which minimal utilization rates are promulgated and applied, under section 1881(b)(1) of the Act, and describe the health and safety requirements that facilities furnishing ESRD care to beneficiaries must meet. These regulations further prescribe the role of ESRD networks in meeting the requirements of section 1881(c) of the Act.

(b) The general objectives of the ESRD program are contained in § 405.2101, and general definitions are contained in § 405.2102. The provisions of §§ 405.2110, 405.2112 and 405.2113 discuss the establishment and activities of ESRD networks, network organizations and membership requirements and restrictions for members of the medical review boards. Sections 405.2120 through 405.2124 discuss the establishment of minimal utilization rates and the requirements for approval of facilities with respect to such rates. Sections 405.2130 through 405.2140 discuss general requirements for, and description of, all facilities furnishing ESRD services. Sections 405.2160 through 405.2164 discuss specific requirements for facilities which furnish

ESRD dialysis services. Sections 405.2170 and 405.2171 discuss specific requirements for facilities which furnish ESRD transplantation services.

[51 FR 30361, Aug. 26, 1986]

§ 405.2101 Objectives of the end-stage renal disease (ESRD) program.

The objectives of the end-stage renal disease program are:

- (a) To assist beneficiaries who have been diagnosed as having end-stage renal disease (ESRD) to receive the care they need;
- (b) To encourage proper distribution and effective utilization of ESRD treatment resources while maintaining or improving the quality of care;
- (c) To provide the flexibility necessary for the efficient delivery of appropriate care by physicians and facilities; and
- (d) To encourage self-dialysis or transplantation for the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for such treatment.

[43 FR 48950, Oct. 19, 1979]

§ 405.2102 Definitions.

As used in this subpart, the following definitions apply:

Agreement. A written document executed between an ESRD facility and another facility in which the other facility agrees to assume responsibility for furnishing specified services to patients and for obtaining reimbursement for those services.

Arrangement. A written document executed between an ESRD facility and another facility in which the other facility agrees to furnish specified services to patients but the ESRD facility retains responsibility for those services and for obtaining reimbursement for them.

Dialysis. A process by which dissolved substances are removed from a patient's

body by diffusion from one fluid compartment to another across a semipermeable membrane. The two types of dialysis that are currently in common use are hemodialysis and peritoneal dialysis.

End-Stage Renal Disease (ESRD). That stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

ESRD facility. A facility which is approved to furnish at least one specific ESRD service (see definition of “ESRD service”). Such facilities are:

(a) *Renal Transplantation Center.* A hospital unit which is approved to furnish directly transplantation and other medical and surgical specialty services required for the care of the ESRD transplant patients, including inpatient dialysis furnished directly or under arrangement. A Renal Transplantation Center may also be a Renal Dialysis Center.

(b) *Renal dialysis center.* A hospital unit which is approved to furnish the full spectrum of diagnostic, therapeutic, and rehabilitative services required for the care of ESRD dialysis patients (including inpatient dialysis furnished directly or under arrangement). A hospital need not provide renal transplantation to qualify as a renal dialysis center.

(c) *Renal dialysis facility.* A unit which is approved to furnish dialysis service(s) directly to ESRD patients.

(d) *Self-dialysis unit.* A unit that is part of an approved renal transplantation center, renal dialysis center, or renal dialysis facility, and furnishes self-dialysis services.

(e) *Special purpose renal dialysis facility.* A renal dialysis facility which is approved under § 405.2164 to furnish dialysis at special locations on a shortterm basis to a group of dialysis patients otherwise unable to obtain treatment in the geographical area. The special locations must be either special

rehabilitative (including vacation) locations serving ESRD patients temporarily residing there, or locations in need of ESRD facilities under emergency circumstances.

ESRD service. The type of care or services furnished to an ESRD patient. Such types of care are:

(a) *Transplantation service.* A process by which (1) a kidney is excised from a live or cadaveric donor, (2) that kidney is implanted in an ESRD patient, and (3) supportive care is furnished to the living donor and to the recipient following implantation.

(b) *Dialysis service—(1) Inpatient dialysis.*

Dialysis which, because of medical necessity, is furnished to an ESRD patient on a temporary inpatient basis in a hospital; (2) *Outpatient dialysis.* Dialysis furnished on an outpatient basis at a renal dialysis center or facility. Outpatient dialysis includes:

(i) *Staff-assisted dialysis.* Dialysis performed by the staff of the center or facility.

(ii) *Self-dialysis.* Dialysis performed, with little or no professional assistance, by an ESRD patient who has completed an appropriate course of training.

(3) *Home dialysis.* Dialysis performed by an appropriately trained patient at home.

(c) *Self-dialysis and home dialysis training.* A program that trains ESRD patients to perform self-dialysis or home dialysis with little or no professional assistance, and trains other individuals to assist patients in performing self-dialysis or home dialysis.

Furnishes directly. The ESRD facility provides the service through its own staff and employees, or through individuals who are under direct contract to furnish such services personally for the facility (i.e., not through “agreements” or “arrangements”).

Furnishes on the premises. The ESRD facility furnishes services on its main premises; or on its other premises that are

(a) contiguous with or in immediate

proximity to the main premises, and under the direction of the same professional staff and governing body as the main premises, or (b) approved on a time-limited basis as a special purpose renal dialysis facility.

Histocompatibility testing. Laboratory test procedures which determine compatibility between a potential organ donor and a potential organ transplant recipient.

Medical care criteria. Predetermined elements against which aspects of the quality of a medical service may be compared. They are developed by professionals relying on professional expertise and on the professional literature.

Medical care norms. Numerical or statistical measures of usual observed performance. Norms are derived from aggregate information related to the health care provided to a large number of patients over a period of time.

Medical care standards. Professionally developed expressions of the range of acceptable variation from a norm or criterion.

Medical care evaluation study (MCE). Review of health care services, usually performed retrospectively, in which an indepth assessment of the quality and/ or utilization of such services is made.

Network, ESRD. All Medicare-approved ESRD facilities in a designated geographic area specified by CMS.

Network organization. The administrative governing body to the network and liaison to the Federal government.

Organ procurement. The process of acquiring donor kidneys. (See definition of *Organ procurement organization* in § 485.302 of this chapter.)

Qualified personnel. Personnel that meet the requirements specified in this paragraph.

(a) *Chief executive officer.* A person who:
(1) Holds at least a baccalaureate degree or its equivalent and has at least 1 year of experience in an ESRD unit; or

(2) Is a registered nurse or physician director as defined in this definition; or

(3) As of September 1, 1976, has demonstrated capability by acting for at least 2 years as a chief executive officer in a dialysis unit or transplantation program.

(b) *Dietitian.* A person who:

(1) Is eligible for registration by the American Dietetic Association under its requirements in effect on June 3, 1976, and has at least 1 year of experience in clinical nutrition; or

(2) Has a baccalaureate or advanced degree with major studies in food and nutrition or dietetics, and has at least 1 year of experience in clinical nutrition.

(c) *Medical record practitioner.* A person who:

(1) Has graduated from a program for Medical Record Administrators accredited by the Council on Medical Education of the American Medical Association and the American Medical Record Association, and is eligible for certification as a Registered Record Administrator (RRA) by the American Medical Record Association under its requirements in effect on June 3, 1976.

(2) Has graduated from a program for Medical Record Technicians approved jointly by the Council on Medical Education of the American Medical Association and the American Medical Record Association, and is eligible for certification as an Accredited Record Technician (ART) by the American Medical Record Association under its requirements in effect June 3, 1976, or

(3) Has successfully completed and received a satisfactory grade in the American Medical Record Association's Correspondence Course for Medical Record Personnel approved by the Accrediting Commission of the National Home Study Council, and is eligible for certification as an Accredited Record Technician by the American

Medical Record Association under its requirements in effect June 3, 1976.

(d) *Nurse responsible for nursing service.*

A person who is licensed as a registered nurse by the State in which practicing, and (1) has at least 12 months of experience in clinical nursing, and an additional 6 months of experience in nursing care of the patient with permanent kidney failure or undergoing kidney transplantation, including training in and experience with the dialysis process; or (2) Has 18 months of experience in nursing care of the patient on maintenance dialysis, or in nursing care of the patient with a kidney transplant, including training in and experience with the dialysis process; (3) If the nurse responsible for nursing service is in charge of self-care dialysis training, at least 3 months of the total required ESRD experience is in training patients in self-care.

(e) *Physician-director.* A physician who:

(1) Is board eligible or board certified in internal medicine or pediatrics by a professional board, and has had at least 12 months of experience or training in the care of patients at ESRD facilities; or (2) During the 5-year period prior to September 1, 1976, served for at least 12 months as director of a dialysis or transplantation program; (3) In those areas where a physician who meets the definition in paragraph (1) or (2) of this definition is not available to direct a participating dialysis facility, another physician may direct the facility, subject to the approval of the Secretary.

(f) **Social worker.** A person who is licensed, if applicable, by the State in which practicing, and

(1) Has completed a course of study with **specialization in clinical practice** at, and holds a **masters degree from, a graduate school of social work accredited by the Council on Social Work Education**; or

(2) Has served for at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under paragraph (f)(1) of this definition.

(g) *Transplantation surgeon.* A person who:

(1) Is board eligible or board certified in general surgery or urology by a professional board; and

(2) Has at least 12 months training or experience in the performance of renal transplantation and the care of patients with renal transplants.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48950, Oct. 19, 1978; 51 FR 30361, Aug. 26, 1986; 53 FR 6547, Mar. 1, 1988; 55 FR 9575, Mar. 14, 1990]

§ 405.2110 Designation of ESRD networks.

CMS designated ESRD networks in which the approved ESRD facilities collectively provide the necessary care for ESRD patients.

(a) *Effect on patient choice of facility.*

The designation of networks does not require an ESRD patient to seek care only through the facilities in the designated network where the patient resides, nor does the designation of networks limit patient choice of physicians or facilities, or preclude patient referral by physicians to a facility in another designated network.

(b) *Redesignation of networks.* CMS will redesignate networks, as needed, to ensure that the designations are consistent with ESRD program experience, consistent with ESRD program objectives specified in § 405.2101, and compatible with efficient program administration.

[51 FR 30361, Aug. 26, 1986]

§ 405.2111 [Reserved]

§ 405.2112 ESRD network organizations.

CMS will designate an administrative governing body (network organization) for each network. The functions of a network organization include but are not limited to the following:

- (a) Developing network goals for placing patients in settings for selfcare and transplantation.
- (b) Encouraging the use of medically appropriate treatment settings most compatible with patient rehabilitation and the participation of patients, providers of services, and renal disease facilities in vocational rehabilitation programs.
- (c) Developing criteria and standards relating to the quality and appropriateness of patient care and, with respect to working with patients, facilities, and providers of services, for encouraging participation in vocational rehabilitation programs.
- (d) Evaluating the procedures used by facilities in the network in assessing patients for placement in appropriate treatment modalities.
- (e) Making recommendations to member facilities as needed to achieve network goals.
- (f) On or before July 1 of each year, submitting to CMS an annual report that contains the following information:
 - (1) A statement of the network goals.
 - (2) The comparative performance of facilities regarding the placement of patients in appropriate settings for—
 - (i) Self-care;
 - (ii) Transplants; and
 - (iii) Vocational rehabilitation programs.
 - (3) Identification of those facilities that consistently fail to cooperate with the goals specified under paragraph (f)(1) of this section or to follow the recommendations of the medical review board.
 - (4) Identification of facilities and providers that are not providing appropriate medical care.

- (5) Recommendations with respect to the need for additional or alternative services in the network including selfdialysis training, transplantation and organ procurement.
- (g) Evaluating and resolving patient grievances.
- (h) Appointing a network council and a medical review board (each including at least one patient representative) and supporting and coordinating the activities of each.
- (i) Conducting on-site reviews of facilities and providers as necessary, as determined by the medical review board or CMS, using standards of care as specified under paragraph (c) of this section.
- (j) Collecting, validating, and analyzing such data as necessary to prepare the reports required under paragraph (f) of this section and the Secretary's report to Congress on the ESRD program and to assure the maintenance of the registry established under section 1881(c)(7) of the Act.

[53 FR 1620, Jan. 21, 1988]

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§ 405.2137 Condition: Patient longterm program and patient care plan.

Each facility maintains for each patient a written long-term program and a written patient care plan to ensure that each patient receives the appropriate modality of care and the appropriate care within that modality. The patient, or where appropriate, parent or legal guardian is involved with the health team in the planning of care. A copy of the current program and plan accompany the patient on interfacility transfer.

(a) *Standard: patient long-term program.*

There is a written long-term program representing the selection of a suitable treatment modality (i.e., dialysis or transplantation) and dialysis setting (e.g., home, self-care) for each patient.

- (1) The program is developed by a professional team which includes but is not

limited to the physician director of the dialysis facility or center where the patient is currently being treated, a physician director of a center or facility which offers self-care dialysis training (if not available at the location where the patient is being treated), a transplant surgeon, a qualified nurse responsible for nursing services, a qualified dietitian and a **qualified social worker**.

(2) The program is formally reviewed and revised in writing as necessary by a team which includes but is not limited to the physician director of the dialysis facility or center where the patient is presently being treated, in addition to the other personnel listed in paragraph (a)(1) of this section at least every 12 months or more often as indicated by the patient's response to treatment (see § 405.2161(b)(1) and § 405.2170(a)).

(3) The patient, parent, or legal guardian, as appropriate, is involved in the development of the patient's longterm program, and due consideration is given to his preferences.

(4) A copy of the patient's long-term program accompanies the patient on interfacility transfer or is sent within 1 working day.

(b) *Standard: patient care plan.* There is a written patient care plan for each patient of an ESRD facility (including home dialysis patients under the supervision of the ESRD facility; see § 405.2163(e)), based upon the nature of the patient's illness, the treatment prescribed, and an assessment of the patient's needs.

(1) The patient care plan is personalized for the individual, reflects the **psychological, social, and functional needs** of the patient, and indicates the ESRD and other care required as well as the individualized modifications in approach necessary to achieve the longterm and short-term goals.

(2) The plan is developed by a professional team consisting of at least the physician responsible for the patient's ESRD care, a

qualified nurse responsible for nursing services, a **qualified social worker**, and a qualified dietitian.

(3) The patient, parent, or legal guardian, as appropriate, is involved in the development of the care plan, and due consideration is given to his preferences.

(4) The care plan for patients whose medical condition has not become stabilized is reviewed at least monthly by the professional patient care team described in paragraph (b)(2) of this section. For patients whose condition has become stabilized, the care plan is reviewed every 6 months. The care plan is revised as necessary to insure that it provides for the patients ongoing needs.

(5) If the patient is transferred to another facility, the care plan is sent with the patient or within 1 working day.

(6) For a home-dialysis patient whose care is under the supervision of the ESRD facility, the care plan provides for periodic monitoring of the patient's home adaptation, including provisions for visits to the home by qualified facility personnel to the extent appropriate. (See § 405.2163(e).)

(7) Beginning July 1, 1991, for a home dialysis patient, and beginning January 1, 1994, for any dialysis patient, who uses EPO in the home, the plan must provide for monitoring home use of EPO that includes the following:

(i) Review of diet and fluid intake for indiscretions as indicated by hyperkalemia and elevated blood pressure secondary to volume overload.

(ii) Review of medications to ensure adequate provision of supplemental iron.

(iii) Ongoing evaluations of hematocrit and iron stores.

(iv) A reevaluation of the dialysis prescription taking into account the patient's increased appetite and red blood cell volume.

- (v) A method for physician followup on blood tests and a mechanism (such as a patient log) for keeping the physician informed of the results.
 - (vi) Training of the patient to identify the signs and symptoms of hypotension and hypertension.
 - (vii) The decrease or discontinuance of EPO if hypertension is uncontrollable.
- [41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48952, Oct. 19, 1978; 59 FR 1284, Jan. 10, 1994; 59 FR 26958, May 25, 1994]
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§ 405.2162 Condition: Staff of a renal dialysis facility or renal dialysis center.

Properly trained personnel are present in adequate numbers to meet the needs of the patients, including those arising from medical and nonmedical emergencies.

(a) *Standard: Registered nurse.* The dialysis facility employs at least one full time qualified nurse responsible for nursing service. (See § 405.2102.)

(b) *Standard: On-duty personnel.*

Whenever patients are undergoing dialysis:

- (1) One currently licensed health professional (e.g., physician, registered nurse, or licensed practical nurse) experienced in rendering ESRD care is on duty to oversee ESRD patient care;
- (2) An adequate number of personnel are present so that the patient/staff ratio is appropriate to the level of dialysis care being given and meets the needs of patients; and

(3) An adequate number of personnel are readily available to meet medical and nonmedical needs.

(c) *Standard: Self-care dialysis training personnel.* If the facility offers self-care dialysis training, a qualified nurse is in charge of such training (see § 405.2102.) [41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at

43 FR 48953, Oct. 19, 1978; 51 FR 30362, Aug. 26, 1986]

§ 405.2163 Condition: Minimal service requirements for a renal dialysis facility or renal dialysis center.

The facility must provide dialysis services, as well as adequate laboratory, **social**, and dietetic **services** to meet the needs of the ESRD patient.

(a) *Standard: Outpatient dialysis services* —(1) *Staff-assisted dialysis services.*

The facility must provide all necessary institutional dialysis services and staff required in performing the dialysis.

(2) *Self-dialysis services.* If the facility offers self-dialysis services, it must provide all medically necessary supplies and equipment and any other service specified in the facility's patient care policies.

(b) *Standard: Laboratory services.* The dialysis facility makes available laboratory services (other than the specialty of tissue pathology and histocompatibility testing), to meet the needs of the ESRD patient. All laboratory services must be performed by an appropriately certified laboratory in accordance with part 493 of this chapter. If the renal dialysis facility furnishes its own laboratory services, it must meet the applicable requirements established for certification of laboratories found in part 493 of this chapter.

If the facility does not provide laboratory services, it must make arrangements to obtain these services from a laboratory certified in the appropriate specialties and subspecialties of service in accordance with the requirements of part 493 of this chapter.

(c) *Standard: Social services.* **Social services** are provided to patients and their families and are directed at supporting and maximizing the social functioning and adjustment of the patient. Social services are furnished by a **qualified social worker** (§ 405.2102) who has an employment or contractual relationship with the facility.

The qualified social worker is responsible for conducting psychosocial evaluations, participating in team review of patient progress and recommending changes in treatment based on the patient's current psychosocial needs, providing casework and groupwork services to patients and their families in dealing with the special problems associated with ESRD, and identifying community social agencies and other resources and assisting patients and families to utilize them.

(d) *Standard: Dietetic services.* Each patient is evaluated as to his nutritional needs by the attending physician and by a qualified dietician (§ 405.2102) who has an employment or contractual relationship with the facility. The dietician, in consultation with the attending physician, is responsible for assessing the nutritional and dietetic needs of each patient, recommending therapeutic diets, counseling patients and their families on prescribed diets, and monitoring adherence and response to diets.

(e) *Standard: Self-dialysis support services.* The renal dialysis facility or center furnishing self-dialysis training upon completion of the patient's training, furnishes (either directly, under agreement or by arrangement with another ESRD facility) the following services:

- (1) Surveillance of the patient's home adaptation, including provisions for visits to the home or the facility;
- (2) Consultation for the patient with a **qualified social worker** and a qualified dietitian;
- (3) A recordkeeping system which assures continuity of care;
- (4) Installation and maintenance of equipment;
- (5) Testing and appropriate treatment of the water; and
- (6) Ordering of supplies on an ongoing basis.

(f) *Standard: Participation in recipient registry.* The dialysis facility or center participates in a patient registry program with an OPO designated or redesignated under part 486, subpart G of this chapter, for patients who are awaiting cadaveric donor transplantation.

(g) *Use of EPO at home: Patient selection.* The dialysis facility, or the physician responsible for all dialysis-related services furnished to the patient, must make a comprehensive assessment that includes the following:

(1) *Pre-selection monitoring.* The patient's hematocrit (or hemoglobin), serum iron, transferrin saturation, serum ferritin, and blood pressure must be measured.

(2) *Conditions the patient must meet.* The assessment must find that the patient meets the following conditions:

(i) On or after July 1, 1991, is a home dialysis patient or, on or after January 1, 1994, is a dialysis patient;

(ii) Has a hematocrit (or comparable hemoglobin level) that is as follows:

(A) For a patient who is initiating EPO treatment, no higher than 30 percent unless there is medical documentation showing the need for EPO despite a hematocrit (or comparable hemoglobin level) higher than 30 percent. (Patients with severe angina, severe pulmonary distress, or severe hypertension may require EPO to prevent adverse symptoms even if they have higher hematocrit or hemoglobin levels.)

(B) For a patient who has been receiving EPO from the facility or the physician, between 30 and 33 percent.

(iii) Is under the care of—

(A) A physician who is responsible for all dialysis-related services and who prescribes the EPO and follows the drug labeling instructions when monitoring the EPO home therapy; and

(B) A renal dialysis facility that establishes the plan of care and monitors the progress of the home EPO therapy.

(3) *Conditions the patient or the patient's caregiver must meet.* The assessment must find that the patient or a caregiver who assists the patient in performing self-dialysis meets the following conditions:

(i) Is trained by the facility to inject EPO and is capable of carrying out the procedure.

(ii) Is capable of reading and understanding the drug labeling.

(iii) Is trained in, and capable of observing, aseptic techniques.

(4) *Care and storage of drug.* The assessment must find that EPO can be stored in the patient's residence under refrigeration and that the patient is aware of the potential hazard of a child's having access to the drug and syringes.

(h) *Use of EPO at home: Responsibilities of the physician or the dialysis facility.*

The patient's physician or dialysis facility must—

(1) Develop a protocol that follows the drug label instructions;

(2) Make the protocol available to the patient to ensure safe and effective home use of EPO; and

(3) Through the amounts prescribed, ensure that the drug "on hand" at any time does not exceed a 2-month supply.

[43 FR 48953, Oct. 19, 1978, as amended at 51 FR 30362, Aug. 26, 1986; 57 FR 7134, Feb. 28, 1992; 59 FR 1284, Jan. 10, 1994; 59 FR 26958, May 25, 1994; 59 FR 46513, Sept. 8, 1994; 61 FR 19743, May 2, 1996]

§ 405.2164 Conditions for coverage of special purpose renal dialysis facilities.

(a) A special purpose renal dialysis facility must comply with all conditions for coverage for renal dialysis facilities specified in §§ 405.2130 through 405.2164, with the exception of §§ 405.2134, and 405.2137 that relate to participation in the

network activities and patient long-term programs.

(b) A special purpose renal dialysis facility must consult with a patient's physician to assure that care provided in the special purpose dialysis facility is consistent with the patient's longterm program and patient care plan required under § 405.2137.

(c) The period of approval for a special purpose renal dialysis facility may not exceed 8 calendar months in any calendar year.

(d) A special purpose renal dialysis facility may provide services only to those patients who would otherwise be unable to obtain treatments in the geographical areas served by the facility.

[48 FR 21283, May 11, 1983, as amended at 51 FR 30362, Aug. 26, 1986]

§ 405.2170 Condition: Director of a renal transplantation center.

The renal transplantation center is under the general supervision of a qualified transplantation surgeon (§ 405.2102) or a qualified physician-director (§ 405.2102), who need not serve full time. This physician is responsible for planning, organizing, conducting, and directing the renal transplantation center and devotes sufficient time to carry out these responsibilities, which include but are not limited to the following:

(a) Participating in the selection of a suitable treatment modality for each patient.

(b) Assuring adequate training, of nurses in the care of transplant patients.

(c) Assuring that tissue typing and organ procurement services are available either directly or under arrangement.

(d) Assuring that transplantation surgery is performed under the direct supervision of a qualified transplantation surgeon.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 51 FR 30362, Aug. 26, 1986; 59 FR 46514, Sept. 8, 1994]

§ 405.2171 Condition: Minimal service requirements for a renal transplantation center.

Kidney transplantation is furnished directly by a hospital that is participating as a provider of services in the Medicare program and is approved by CMS as a renal transplantation center. The renal transplantation center is under the overall direction of a hospital administrator and medical staff; if operated by an organizational subsidiary, it is under the direction of an administrator and medical staff member (or committee) who are directly responsible to the hospital administrator and medical staff, respectively. Patients are accepted for transplantation only on the order of a physician and their care continues under the supervision of a physician.

(a) *Standard: participation in recipient registry.* The renal transplantation center participates in a patient registry program with an OPO certified or recertified under part 485, subpart D of this chapter for patients who are awaiting cadaveric donor transplantation.

(b) *Standard: social services.* **Social services** are provided to patients and their families and are directed at supporting and maximizing the social functioning and adjustment of the patient. Social services are furnished by a qualified social worker (§ 405.2102) who has an employment or contractual relationship with the facility. The qualified social worker is responsible for conducting psychosocial evaluations, participating in team review of patient progress and recommending changes in treatment based on the patient's current psychosocial needs, providing casework and groupwork services to patients and their families in dealing with the special problems associated with ESRD, and identifying community social agencies and other resources and assisting patients and families to utilize them.

(c) *Standard: dietetic services.* Each patient is evaluated as to his nutritional needs by the attending physician and a qualified dietician (§ 405.2102) who has an employment or contractual relationship with the facility. The dietician, in consultation with the attending

physician, is responsible for assessing the nutritional and dietetic needs of each patient, recommending therapeutic diets, counseling patients and their families on prescribed diets, and monitoring adherence and response to diets. (d) *Standard: Laboratory services:* (1) The renal transplantation center makes available, directly or under arrangements, laboratory services to meet the needs of ESRD patients. Laboratory services are performed in a laboratory facility certified in accordance with part 493 of this chapter.

(2) Laboratory services for crossmatching of recipient serum and donor lymphocytes for pre-formed antibodies by an acceptable technique are available on a 24-hour emergency basis.

(e) *Standard: Organ procurement.* A renal transplantation center using the services of an organ procurement organization designated or redesignated under part 485, subpart D of this chapter to obtain donor organs has a written agreement covering these services. The renal transplantation center agrees to notify CMS in writing within 30 days of the termination of the agreement.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 51 FR 30362, Aug. 26, 1986; 53 FR 6548, Mar. 1, 1988; 57 FR 7134, Feb. 28, 1992; 59 FR 46514, Sept. 8, 1994]

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