UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
TRENTON VICINAGE

STATE OF NEW JERSEY,	
Plaintiff,	
v.	Hon. JOEL A. PISANO
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,	Civil Action No. 3:07-cv-04698 (JAP)
Defendant.	

JOINT BRIEF OF *AMICUS CURIAE* NEW JERSEY APPLESEED PUBLIC INTEREST LAW CENTER and ADDITIONAL *AMICI CURIAE* NEW JERSEY CITIZEN ACTION; FAMILY VOICES OF NEW JERSEY; ALLIANCE FOR DISABLED IN ACTION; NEXT STEP; BLUEWAVE NJ; THE ELDER RIGHTS ALLIANCE OF NEW JERSEY; CWA-LOCAL 1037; CWA-LOCAL 1034; CATHOLIC CHARITIES-DIOCESE OF TRENTON; HEALTH PROFESSIONAL AND ALLIED EMPLOYEES; HEALTHCARE FOR ALL/NJ; STATEWIDE PARENT ADVOCACY NETWORK; ALLIANCE FOR THE BETTERMENT OF CITIZENS WITH DISABILITIES; THE WORKMEN'S CIRCLE/ARBETER RING NEW JERSEY REGION; NATIONAL ASSOCIATION OF SOCIAL WORKERS AND ITS NEW JERSEY CHAPTER; AND NATIONAL ORGANIZATION FOR WOMEN-MORRIS COUNTY CHAPTER IN SUPPORT OF PLAINTIFF'S OPPOSITION TO DEFENDANT'S MOTION TO DISMISS AND CROSS-MOTION FOR PARTIAL SUMMARY JUDGMENT

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STATEMENT OF INTEREST OF AMICI CURIAE

A. New Jersey Appleseed Public Interest Law Center

New Jersey Appleseed is a not-for-profit, non-partisan organization that plays a critical role in protecting and advancing the rights and interests of New Jersey residents by addressing systemic social and political problems and ensuring that the needs and concerns of the most underserved and under-represented groups in the state are addressed. It currently serves on the Leadership Team of the Robert Wood Johnson funded Voices for Coverage Coalition. New Jersey Appleseed has a substantial interest in protecting the health and welfare of low-income children who reside in New Jersey, and in particular in insuring that New Jersey is able to design its health programs to guarantee that these low-income children have access to adequate health care.

B. Additional Amici

The Alliance for the Betterment of Citizens with Disabilities ("ABCD") is a statewide advocacy organization that represents 17 member agencies that provide a broad array of community based services to more than 10,000 individuals with developmental disabilities and their families. The mission of ABCD, an association of non-profit organizations, is to affect the development and implementation of public policy and to support the member organizations whose specific purpose is to improve the lives of people with multiple physical and developmental disabilities so that they have the opportunity to attain the highest level of purpose and dignity. ABCD also represents the Early Intervention Providers Association ("EIPA"). EIPA's membership provides services collectively to over 50% of New Jersey's children and families in the Early Intervention system. ABCD has a special interest in ensuring that its beneficiaries have health care insurance.

The Alliance for Disabled in Action ("ADA") is an Independent Living Center serving people with disabilities in Middlesex, Somerset and Union Counties. It is an I.R.C. 501(c)(3) organization, and seeks to provide a broad number of services to persons with disabilities in order to enable them to live independent and fulfilling lives. The ADA therefore has a special interest in ensuring that the State of New Jersey has the ability to provide health insurance to a large number of its residents.

BlueWaveNJ is a grassroots organization working to protect and improve the rights, opportunities, and quality of life of all people through direct advocacy, public education on critical issues, and community mobilization. In order to fulfill its mission to find solutions through community, the group created issue-based working groups to implement its goals, including a group on health insurance. BlueWaveNJ believes that is vital to the health of people residing in New Jersey that the State has the ability to implement its SCHIP program in the broadest possible manner; thus, it has a special interest in this litigation.

Catholic Charities, Diocese of Trenton, a faith-inspired human service agency with over 100 years of experience, provides professional social services to a diverse range of human service populations through 58 programs at 34 service sites and 72 residential sites in Burlington, Mercer, Monmouth, and Ocean Counties. Catholic Charities provides nonreligious-based assistance regardless of race, faith, sexual orientation, or gender to more than 100,000 people in need each year and touches the lives of one in every 19 residents of central New Jersey. As a result, it sees first hand how not having adequate health insurance impacts families, especially children. Many of the families who seek basic needs assistance from Catholic Charaties (food, clothing and shelter) also do no have health insurance. They often seek help with overdue rent as they have had to pay for medication and doctor's visits. Even those who earn 350% of the

Federal Poverty Level struggle with paying bills and are relieved to have insurance. So, Catholic Charities has a special interest in this litigation.

CWA Local 1034 is a New Jersey State Worker union local of the Communications Workers of America. The local has over 15,000 members in State, County, and Local government. It is the largest public workers local in the country. The executive board of Local 1034 join in this amicus brief because of its concern for the health of the children of New Jersey and the negative impact CMS policy would have under the new rules.

CWA Local 1037 represents approximately 12,000 public and social service workers. It is participating in this lawsuit as an *amicus curiae* primarily for two reasons. First, as the representative of persons employed by the Department of Youth and Family Services, Local 1037 has observed the significant correlation between lack of healthcare and poverty, and the correlation between poverty and child abuse and neglect. It accordingly has a special interest in seeing the maximum number of children insured pursuant to S-CHIP. Second, Local 1037 represents approximately 3000 direct care workers, who work full time, sometimes at more than one job, and who are almost all currently entitled to S-CHIP for their children. These workers provide direct care for disabled individuals and home child care for welfare to work clients. They work full time and their newly received higher wages have finally pushed their families over the margins of poverty. But if they had to pay higher premiums for healthcare costs for their children, those gains would vanish, and would likely result in their children becoming uninsured. Accordingly, Local 1037 has a special interest in seeing that New Jersey is able to keep its S-CHIP income eligibility levels at 350% of the federal poverty line.

The Elder Rights Alliance of New Jersey was founded to advocate and educate in favor of the rights of senior citizens and all persons, especially in the area of health care. The Elder

Rights Alliance believes that is vital to the health of people residing in New Jersey that the State has the ability to implement its S-CHIP program in the broadest possible manner; thus, it has a special interest in this litigation.

Family Voices of New Jersey is New Jersey's chapter of Family Voices, a national grassroots network of families and friends, that: advocates for health care services that are family-centered, community-based, comprehensive, coordinated and culturally competent for all children and youth with special health care needs; promotes the inclusion of all families as decision makers at all levels of health care; and supports essential partnerships between families and professionals. Family Voices of New Jersey assists families of children and youth with special healthcare needs to access the services and support their children need to maximize their healthy development. Family Voices asserts the new CMS requirements will interfere with New Jersey's attempts to insure all children through the current SCHIP program and may interfere with its ability to expand coverage by offering full cost buy-ins to those families with incomes above 350% of the federal poverty level. Particularly for families of children with special healthcare needs, SCHIP coverage is essential to ensure that their children receive the health promotion, prevention, and intervention services that are critical to their continued ability to live in their homes and communities. As a health care advocate for children and youth, Family Voices has a special interest in this litigation.

Health Care for All/NJ, which has about 125 members, advocates for Universal Health Care. It supports all efforts, including the position taken in this brief, which seek to enlarge the numbers of insured citizens and oppose initiatives that would shrink those numbers.

Health Professionals and Allied Employees ("HPAE") is a 12,000 member health care union representing nurses, technicians, social workers and research professionals in 11 hospitals

and 3 nursing homes in New Jersey. HPAE is a strong public advocate for healthcare access, safe patient care and the rights of health care workers. HPAE is active in citizen coalitions throughout NJ on behalf of quality health care, and thus has a special interest in the outcome of this litigation.

National Association of Social Workers ("NASW") was established in 1955 and is the largest association of professional social workers in the world, with 145,000 members and chapters throughout the United States, including New Jersey, and elsewhere in the world. The New Jersey Chapter of NASW has 7,600 members. Its purpose includes developing and disseminating standards of social work practice while strengthening and unifying the social work profession as a whole. Toward that end, NASW provides continuing education, enforces the *NASW Code of Ethics*, conducts research, publishes books and studies, promulgates professional criteria, and develops policy statements on issues of importance to the social work profession. NASW also supports and advocates for the development of programs for youths. Specifically, because it supports all "efforts to enlarge health care coverage to uninsured and underinsured people until universal health and mental health coverage is achieved," it has a special interest in this litigation.

National Organization for Women – Morris County Chapter ("NOW") takes action to bring women into full participation in the mainstream of American society, exercising all privileges and responsibilities thereof in truly equal partnership with men. This includes, but is not limited to, equal rights and responsibilities in all aspects of citizenship, public service, employment, education, and family life, and it includes freedom from discrimination because of race, creed, color, sex, religion, national or ethnic origin, age, economic status, marital status, parenthood, physical ability, political affiliations, sexual orientation or lifestyle. NOW has a

special interest in this litigation that directly affects on low-income women and their ability to ensure that their children receive health insurance coverage.

New Jersey Citizen Action ("NJCA") is the state's largest, independent citizen watchdog coalition, working to protect and expand the rights of individuals and families and to ensure that government officials respond to the needs of people rather than the interests of those with money and power. Through organizing campaigns that promote economic, social, racial and political justice, NJCA encourages the active involvement of New Jersey residents in challenging the public and private institutions and agencies that affects our lives. NJCA believes that all people should have guaranteed access to high quality, affordable healthcare. Through its SCHIP program known as FamilyCare, New Jersey ensures that thousands of low-income children and families in the State have access to healthcare. The August 17, 2007 CMS directive inhibits the State's ability to provide children and families with access to health insurance and is antithetical to the goal of achieving universal healthcare in New Jersey and across the nation. Accordingly, NJCA has a special interest in this litigation in which the State of New Jersey seeks to enjoin the implementation of the CMS directive.

Next Step, incorporated as People with Disabilities for Social and Economic Justice, is a grassroots movement that attacks the root causes as well as the symptoms of the social and economic exclusion of people with disabilities and other devalued groups through non-violent strategies and tactics of social change. It does so in coalition with others who share its goals and values. Next Step has a special interest in ensuring that all people with disabilities are guaranteed access to high quality, affordable health care, and therefore have a special interest in this litigation.

Statewide Parent Advocacy Network ("SPAN") empowers families and concerned professionals to advocate on behalf of the education and healthy development of New Jersey's children. SPAN provides information, training, technical assistance and support to families on issues affecting their children, including health care, health coverage, and mental health services, education, child care, language access, child welfare, and family support, among other issues. SPAN's primary commitment is to those children and families at greatest risk due to poverty, special health or mental health needs, discrimination based on race, language, or immigrant status, or involvement in the juvenile justice or child welfare systems. SPAN houses New Jersey's Family to Family Health Information and Resource Center, which connects families to health resources and supports for their children, particularly children with special healthcare needs. SPAN's commitment to meeting the health care needs of vulnerable children in New Jersey gives it a special interest in this litigation.

The Workmen's Circle/Arbeter Ring New Jersey Region ("Workmen's Circle") was formed more than 100 years ago by Jewish immigrants from Eastern Europe as a fraternal benefit society, providing much needed social service for working families, including sick benefits, funeral/burial services and educational programs. Today, with members and branches throughout the country, The Workmen's Circle promotes Jewish culture and community and social and economic justice. It continues to focus on access to quality, affordable health care as a basic right especially in our work in New Jersey. The Workmen's Circle therefore has a special interest in this litigation.

*** * * * ***

INTRODUCTION

New Jersey Appleseed Public Interest Law Center and the 16 other entities described above, as *amici curiae*, respectfully urge the Court to deny Defendant's Motion to Dismiss and grant Plaintiff's Cross Motion for Partial Summary Judgment. As discussed more fully below, the August 17, 2007 policy letter (the "CMS Letter") issued by the Centers for Medicare and Medicaid Services ("CMS") sets forth rigid, unattainable, and illegal benchmarks for state child health plans under the State Children's Health Insurance Program, 42 U.S.C. §§ 1397aa-jj (2006) ("SCHIP"). *See* Letter from Dennis G. Smith, Dir., CMS, to State Health Officials (Aug. 17, 2007) ("CMS Letter"); a copy is attached hereto for the Court's convenience as Ex. 1. The SCHIP statute grants states broad discretion to develop individualized programs, and New Jersey's SCHIP program, which has been repeatedly approved by CMS, has achieved great success since its inception in 1998. Its annual enrollment has risen to approximately 150,000 children in the state – children who would otherwise be uninsured without the program. Furthermore, lack of insurance among children has fallen significantly, well-child exams have increased, and unmet health care needs have decreased. The CMS Letter constitutes a sudden and illegal reversal of long-standing federal policy and CMS's prior approvals of the New Jersey SCHIP program; if allowed to stand, it will have a real, immediate, and detrimental impact on New Jersey's SCHIP program and on the children it serves, undermining advances made in New Jersey and resulting in the denial of coverage to thousands of low-income children who are currently and properly insured under the program.

Background

The purpose of SCHIP, which is more fully described in the Complaint, ¶¶ 8-22, is to initiate and expand the provision of child health assistance to uninsured children in low-income

families in an effective and efficient manner that is coordinated with other sources of health benefits coverage for children. 42 U.S.C. § 1397aa (2006). As the Complaint notes, New Jersey's initial State Plan, approved by CMS in February 1998, provided SCHIP-funded insurance coverage to children in families with gross incomes up to 200 percent of the federal poverty level ("FPL")[1]. Compl. ¶ 25. In 1999, CMS approved an amendment that expanded coverage to children in families with gross incomes between 200 and 350 percent of the FPL. Compl. ¶ 26.

In the ten (10) years since its inception, New Jersey has provided coverage to an increasing number of children, as the table below illustrates:

Year	Number of Children Ever Enrolled
1998	Not reported
1999	75,652
2000	89,034
2001	99,847
2002	117,053
2003	119,272
2004	127,244
2005	129,591
2006	142,805
2007	150,277

FY 1999 through 2007 SCHIP Annual Enrollment Reports; copies are attached hereto as Ex. 3.

Today, New Jersey provides access to health care through Medicaid and SCHIP to approximately 150,000 children who likely would otherwise be uninsured. Success in enrollment has translated to a dramatic drop in the number of children who are not covered by any insurance, particularly those children in low-income households. The number of uninsured low-income children in New Jersey decreased 27.1 percent between 1996 and 2004. New Jersey

[1] The 2008 FPL for a family of four is $21,200. Annual Update of the HHS Poverty Guidelines, 73 Fed. Reg. 3,971–72 (Jan. 23, 2008); a copy is attached hereto as Ex. 2.

Annual Report to CMS Federal Fiscal Year 2005 ("2005 Annual Report") at 22, relevant excerpts are attached hereto as Ex. 4.

New Jersey's SCHIP program also has proven successful as measured by CMS's own core health standards. For example, the percentage of enrolled children with six or more well-child visits during the first 15 months of life increased from 31 percent in 2001 to 48 percent in 2005. 2005 Annual Report at 13–14; New Jersey Annual Report to CMS Federal Fiscal Year 2004 ("2004 Annual Report") at 12–13; relevant excerpts from these reports are attached hereto as Ex. 5. In addition, the percentage of enrolled children completing well-child visits in the third, fourth, fifth, and sixth years of life climbed from 56 percent to 72 percent during the same period. 2005 Annual Report at 14–15; 2004 Annual Report at 13–14.

A 2002 study highlights New Jersey's success story, observing that NJ FamilyCare enrollees enjoy greater access to and use of doctors, dentists, and mental health professionals. Genevieve Kenney et al., Mathematica Policy Research, Inc. and The Urban Inst., *The Experience of SCHIP Enrollees and Disenrollees in 10 States: Findings from the Congressionally Mandated SCHIP Evaluation* 236 (Oct. 31, 2005); relevant excerpts are attached hereto as Ex. 6. Enrollees also have fewer visits to the emergency room. *Id.* In addition, unmet health needs in New Jersey have decreased across the board for doctor care, dental care, specialist care, hospital care, and prescription drugs. *Id.*

The CMS Letter

The CMS Letter requires states that have expanded SCHIP eligibility above an effective level of 250 percent of the federal poverty line ("FPL") to amend their SCHIP plan by August 2008 in the following respects:

- the cost sharing requirement under the state plan must not be more favorable as compared to competing private plans by more than one percent of family income, unless the state plan's cost sharing is capped at five percent of family income;
- the state must establish a minimum of a one-year period of uninsurance before providing coverage; and
- monitoring and verification must include information regarding coverage provided by a noncustodial parent.

CMS Letter at 2. In addition, the CMS Letter requires states to make the following assurances with regard to their SCHIP program:

- at least ninety-five (95) percent of the children in the state below 200 percent of the FPL who are eligible for either SCHIP or Medicaid are enrolled;
- the number of children in the target population insured through private employers has not decreased by more than two (2) percentage points over the prior five-year period; and
- the state is current with all reporting requirements in SCHIP and Medicaid and reports on a monthly basis data relating to the crowd-out requirements.

Id. Because New Jersey expanded eligibility under its SCHIP program from 200 percent to 350 percent of the FPL in 1999 – with CMS's approval – the requirements of the CMS Letter require New Jersey to alter its SCHIP program dramatically.

ARGUMENT

Defendant's Motion to Dismiss asserts two alternative grounds for dismissal: (1) that this Court lacks jurisdiction to hear this appeal; and (2) that the CMS Letter is not subject to notice and comment rulemaking. Both arguments lack merit.

I. THIS COURT HAS JURISDICTION TO HEAR THIS CASE

Defendant's jurisdictional argument is two-fold, contending first that this case is not ripe for judicial review, and second that the Administrative Procedures Act ("APA") and the SCHIP statute preclude review by this Court. In making these arguments, Defendant ignores the law and irrefutable facts that belie its contentions. Immediate judicial review in this Court is particularly appropriate in light of the facial invalidity of the CMS Letter.

A. This Case is Ripe for Judicial Review

The ripeness requirement for judicial review prevents courts from "entangling themselves in abstract disagreements." *Abbott Labs. v. Gardner*, 387 U.S. 136, 148 (1967). Moreover, it ensures that a case involves "a real and substantial controversy admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." *North Carolina v. Rice*, 404 U.S. 244, 246 (1971) (quotation omitted).

In determining whether a case is ripe, a court generally will examine "the fitness of the issues for judicial decision" and "the hardship of the parties of withholding court consideration." *Surrick v. Killion*, 449 F.3d 520, 527 (3d Cir. 2006) (quoting *Abbott Labs.*, 387 U.S. at 149). The U.S. Court of Appeals for the Third Circuit has established a three-part test for determining whether a court will engage in pre-enforcement review in the context of a declaratory judgment action: (1) the parties must have adverse legal interests; (2) the facts must be sufficiently concrete to allow for a conclusive legal judgment; and (3) the judgment must be useful to the parties. *Step-Saver Data Sys., Inc. v. Wyse Tech.*, 912 F.2d 643, 647 (3d Cir. 1990). The controversy presented to the Court here satisfies each of these elements.

1. The Parties Have Substantial Adverse Legal Interests

In assessing the adversity of the parties' interest, courts look to "[w]hether the claim involves uncertain and contingent events, or presents a real and substantial threat of harm." *NE Hub Partners, L.P. v. CNG Transmission Corp.*, 239 F.3d 333, 342 n.9 (3d Cir. 2001). It is not necessary for the party seeking review to have suffered a completed harm in order to establish adversity of interest, so long as there is a substantial threat of real harm that remains throughout the course of the litigation. *Presbytery of N.J. v. Florio*, 40 F.3d 1454, 1463 (3d Cir. 1994).

As described below, the CMS Letter's directives require an immediate and significant change in the way that New Jersey conducts the affairs of its SCHIP program, to the detriment of thousands of low-income children. The CMS Letter is framed in mandatory terms and presents rigorous guidelines the New Jersey SCHIP program as it is currently operating does not – and in some instances, cannot – meet. Thus, its impact is unquestionably real and immediate.

a. The CMS Letter Has an Immediate Effect on New Jersey's Current SCHIP Program Waiting Period

New Jersey's SCHIP program currently requires a three-month waiting period between loss of private insurance coverage and eligibility for its program. N.J. Admin. Code § 10:78-3.6(c)(2) (2008). The CMS Letter, in contrast, requires a minimum one-year waiting period. *See* CMS Letter at 2. Compliance will require a substantial change in the State Plans of New Jersey and a number of other states. In 2006, of the thirty-five states with SCHIP programs that had waiting periods, sixteen had a six-month waiting period (the most common) and eleven others required only a three-month waiting period (second most common). Congressional Budget Office, *The State Children's Health Insurance Program* 11 (May 2007); relevant excerpts are attached hereto as Ex. 7. Only one state had a waiting period that was longer than six months. *Id.*

b. Neither New Jersey nor any Other State Can Meet the 95% Enrollment Rate

No SCHIP program has ever achieved a 95% percent enrollment rate as required by the CMS Letter. *See* Cindy Mann & Michael Odeh, Georgetown University Health Policy Institute, *Moving Backward: Status Report on the Impact of the August 17 SCHIP Directive To Impose New Limits on States' Ability to Cover Uninsured Children* 2 (Dec. 2007); relevant excerpts are attached hereto as Ex. 8. The aggregate SCHIP/Medicaid enrollment rates have been estimated

at seventy-two (72) percent for the United States and sixty-three (63) percent for New Jersey. Georgetown University Health Policy Institute, *Medicaid/SCHIP Participation Rate Among Low-Income Children Under 19, 2005–2006*, (Jan. 7, 2008); a copy is attached hereto as Ex. 9.

New Jersey has taken significant steps to increase it enrollment, including an outreach program that has been in place since the inception of its SCHIP state plan. *See* New Jersey Original State Plan Application 15–16 (Sept. 12, 1997); New Jersey Current State Plan 6–13 (Aug. 24, 2001; "NJ Current Plan"); relevant excerpts for these reports are attached hereto as Ex. 10. The New Jersey program is intended to bolster public awareness, provide targeted outreach, and enhance community and consumer education. New Jersey Title XXI Program & Title XXI Amendment Fact Sheet 4 (Oct. 9, 2007); relevant excerpts are attached hereto as Ex. 11. New Jersey also has engaged in efforts to simplify enrollment and renewal procedures to encourage participation in its programs. *See, e.g.*, NJ Current Plan at 6. Nevertheless, these and other significant outreach programs have failed to achieve 95 percent enrollment; if, as is likely, a 95 percent enrollment is unattainable, New Jersey will have to drastically alter it SCHIP program.

c. The CMS Letter Will Limit Much Needed Insurance Coverage

The mandatory requirements of the CMS Letter also will limit much needed insurance coverage currently provided to the impoverished children in the state. One study points out that the proposed twelve-month waiting period would place children at risk, especially chronically ill children or those with serious health conditions who would be unable to pay for needed medicine and care. Donna Cohen Ross et al., The Kaiser Comm'n on Medicaid and the Uninsured, *Health Coverage for Children and Families in Medicaid and SCHIP: State Efforts Face New Hurdles* 8 (Jan. 2008) ("New Hurdles"); relevant excerpts are attached hereto as Ex. 12. Access to

preventative and other routine services over the course of the one-year waiting period also would be compromised. *Id.*

Similarly, studies have demonstrated that higher premiums that will result from the CMS Letter's cost-sharing requirement can depress participation in SCHIP programs and promote underutilization of health care by participants. *Id.*; *see also* Samantha Artiga & Molly O'Malley, The Kaiser Comm'n on Medicaid and the Uninsured, *Increasing Premiums and Cost Sharing in Medicaid and SCHIP: Recent State Experiences* 3 (May 2005) ("Recent Experiences"); relevant excerpts are attached hereto as Ex. 13. It can also increase the rate of children disenrolling from SCHIP coverage (for missing a premium payment, for example), but remaining eligible and re-enrolling soon after (so-called "churning"). *See* New Hurdles at 8. Analyses of several state plans demonstrate that cost-sharing, through even nominal or modest premiums and co-payments, leads to "unmet medical need and financial stress." *See* Recent Experiences at 3. Furthermore, loss of insurance coverage often results in increased demands for charity care, emergency room use and strains on clinic resources. *Id.*

The effects of denying coverage for even limited periods of time can be devastating, especially in cases where consistent medical treatment is needed to control the effects of a chronic disease. A recent report in Ambulatory Pediatrics, for example, observed how "insurance gaps could be particularly problematic for children with asthma, since appropriate preventive care for these children depends on frequent, consistent contacts with health care providers." Jill S. Halterman, MD, MPH, Guillermo Montes, PhD, Laura P. Shone, MSW, DrPH, & Peter G. Szilagyi, MD, MPH, *Impact of Health Insurance Gaps on Access to Care Among Children with Asthma in the United States*, 8 Ambulatory Pediatrics 1 at 43 (Jan.–Feb. 2008); relevant excerpts are attached hereto as Ex. 14. The report concluded that "[e]fforts are

needed to ensure uninterrupted coverage for these children." *Id.* Stressing the critical importance of this issue, one of the co-authors of the report later opined: "Allowing prolonged gaps in insurance for children with special needs is unconscionable. It lets them get worse, it costs them more, it costs the rest of us more, [and] it affects their trajectory in life." David Noonan, *Every Breath They Take*, Newsweek, Mar. 3, 2008, at 15 (quoting Laura Shone); a copy is attached hereto as Ex. 15.

d. Enforcement of the CMS Letter is Imminent.

The CMS Letter makes clear that its enforcement is imminent. *See* CMS Letter at 1–2 ("*we will expect that*, for States that expand eligibility above an effective level of 250 percent of the FPL, the specific crowd-out strategies identified in the State child health plan to include all five of the above crowd-out strategies, which incorporate the following components . . .") (emphasis added); *id.* at 2 ("*we will ask* for such a State to make the following assurances . . .") (emphasis added); *id.* at 2 ("*We expect* affected States to amend their SCHIP state plan . . . in accordance with this review strategy within 12 months . . .") (emphasis added). Further, the Defendant admits that the "CMS Administrator may determine at *any time* that a previously approved state child health plan no longer meets approval requirements." Mem. In Supp. of Def.s' Mot. to Dismiss ("Def.'s Br.") at 7 (emphasis added). Dennis Smith confirmed its imminent enforcement in statements he later made before the House Energy & Commerce Subcommittee on Health – specifically, he stated "the 95 [percent] goal is not only achievable, but should be expected and demanded." Statement of Dennis G. Smith, Dir., CMS, to House Energy & Commerce Subcommittee on Health (Jan. 29, 2008); a copy is attached hereto as Ex. 16. He also observed that the CMS Letter set out "procedures and assurances that should be in place when states enroll new applicants with family incomes in excess of 250 percent of the

federal poverty level . . . ." *Id.* Indeed, CMS has at no point expressly disavowed its intent to enforce the rules. *See Presbytery*, 40 F.3d at 1463–68 (failure to disavow intent to prosecute sufficient to create adversity between the parties). The CMS Letter and Defendant's own actions belie the suggestion that the CMS Letter is a nonbinding "interpretive rule" rather than a final, enforceable agency decision. Def.'s Br. at 18-19.

In light of the foregoing, New Jersey is faced with the decision of either immediately overhauling its entire SCHIP program to comply with CMS guidelines or face substantial punitive measures, which include withholding of funds and financial sanctions against the State. *See* 42 U.S.C.A. §§ 1397ff (c) & (d) (2006). These circumstances alone are sufficient to demonstrate an adversity of interest, "where a regulation requires immediate and significant change in the plaintiffs' conduct of their affairs with serious penalties attached to noncompliance, access to the courts . . . under the Declaratory Judgment Act must be permitted, absent a statutory bar or some other unusual circumstances." *Abbott Labs.*, 387 U.S. at 153 (permitting pre-enforcement review of FDA regulation where regulation required plaintiff "to make significant changes in their everyday business practices . . . [or be] exposed to the imposition of strong sanctions"); *Surrick*, 449 F.3d at 528 ("[W]e conclude that the threat of sanctions is sufficiently real and substantial to satisfy the first prong of the *Step-Saver* inquiry . . . [one] does not have to await the consummation of threatened injury to obtain preventative relief. If the injury is certainly impending, that is enough.") (citations and internal quotations omitted); *see also Travelers Ins. Co. v. Obusek*, 72 F.3d 1148, 1154 (3d Cir. 1995) ("[A] party need not decide between attempting to meet the nearly insurmountable burden of establishing that the relevant injury is a mathematical certainty to occur, nor must a party await actual injury before filing suit.

Erecting such barriers would eviscerate the Declaratory Judgment Act and render the relief it was intended to provide illusory.").

Courts have not hesitated to find substantial hardship where, as here, "the enforcement of a statute or regulation is certain and the only impediment to ripeness is simply a delay before the proceedings commence." *See* Erwin Chemerinsky, Fed. Jurisdiction § 2.4.2 (5th ed. 2007); *see also Regional Rail Reorganization Act Cases*, 419 U.S. 102, 143 (1974) ("Where the inevitability of the operation of a statute against certain individuals is patent, it is irrelevant to the existence of a justiciable controversy that there will be a time delay before the disputed provisions will come into effect."); *Lake Carriers' Ass'n v. MacMullan*, 406 U.S. 498, 507–08 (1972) (finding ripe a challenge to a statute forbidding discharge of sewage from boats, even though prosecutions were not imminent, because it was inevitable that the law would be enforced and boat owners would need to begin installing new facilities on their boats in anticipation of the law's implementation).

Despite the foregoing, Defendant maintains that the "only hardship New Jersey faces now is the administrative inconvenience of working with CMS to come to an acceptable state child health plan amendment," which it maintains is insufficient to show a justiciable controversy here. Def.'s Br. at 24. Even *if* Defendant and New Jersey could reach agreement on an acceptable amendment—and there is no guarantee that they can – the Third Circuit has held that unnecessary and undue agency "process" itself can work a sufficient hardship on a party to show adversity. *NE Hub Partners*, 239 F.3d at 343 (finding ripeness as to pre-enforcement review of state permit process, observing that "the hardship is the process itself[:] [p]rocess costs money"). Moreover, the children of New Jersey should not be compelled to bear the uncertainty

and burden of negotiation between the state and CMS over a plan amendment that would not be necessary but for CMS's unlawful action.

In sum, compliance with the guidelines will have an immediate effect on New Jersey by dismantling the innovative aspects of its program that have resulted in a significant increase in the number of enrolled children. As such, and for all of the reasons identified above, the Plaintiff alleges sufficient adversity and hardship to merit judicial review.

2. The Issues Are Sufficiently Concrete to Allow for a Conclusive Legal Judgment

The second *Step-Saver* factor requires the court to consider the fitness of the issue for adjudication to ensure that the declaratory judgment would in fact determine the parties' rights, as distinguished from an advisory opinion based on a hypothetical set of facts. *Surrick*, 449 F.3d at 528. Cases presenting predominantly legal questions are particularly "amenable to a conclusive determination in a pre-enforcement context," and generally require less factual development. *Id.*; s*ee also Armstrong World Indus., Inc. by Wolfson v. Adams,* 961 F.2d 405, 421 (3d Cir. 1992) ("[W]here the question presented is 'predominantly legal,' . . . the need for factual development is not as great.").

Because the issues presented in this case – *i.e.*, whether the CMS Letter has a rational basis and whether CMS was acting outside the scope of its authority – are predominantly legal, Plaintiff has met its burden of establishing this element. *See James Madison Ltd. by Hecht v. Ludwig*, 82 F.3d 1085, 1096 (D.C. Cir. 1996) ("[D]istrict courts reviewing agency action under the APA's arbitrary and capricious standard do not resolve factual issues . . . . Instead, they address a *predominantly legal issue*: Did the agency 'articulate a rational connection between the facts found and the choice made?'") (emphasis added); *Olympus Corp. v. U.S.*, 627 F.Supp. 911, 919 (E.D.N.Y. 1985) (whether disputed agency action was *ultra vires* was "purely legal").

3. A Decision in This Case Would be Useful to All Parties

The final *Step-Saver* prong requires the Court to consider whether a judgment will affect the parties' plans of actions by alleviating legal uncertainty. *Step-Saver*, 912 F.2d at 649 n.9; *see also NE Hub Partners*, 239 F.3d at 342 n.9. This prong, too, is satisfied here. Unless this Court hears this case, New Jersey is faced with the uncertainty of whether it must begin to make significant changes to its current SCHIP program or face the possibility of losing its funding or facing sanctions. Similarly, the very real prospect of such changes or loss of funding creates doubts for children of low-income families as to whether they will receive, or continue to receive, critical health care coverage. New Jersey should not have to wait until August 2008 – or whenever CMS decides to enforce these illegal mandates – to challenge the validity of the CMS Letter. Even if a subsequent challenge finds, as the *amici* believe it would, that the CMS Letter is invalid and unlawful, irreparable harm may already have been done. By exercising its jurisdiction to hear this case now, this Court will avoid such harm by clarifying the "legal relationships so that plaintiffs . . . [can] make responsible decisions about the future." *See Step-Saver*, 912 F.2d at 649.

In light of the foregoing, this Court should find that this controversy is ripe and justiciable.

B. This Court Should Review the CMS Letter Because There is No Other Adequate Remedy

As a variant on its ripeness argument, Defendant also argues that this Court lacks jurisdiction to review the case because the SCHIP statute provides for judicial review by the Third Circuit Court of Appeals of CMS's determination of the approvability of any plan amendment or lack thereof. Def.'s Brief at 25, *et seq*. The review of a specific application of the

CMS Letter at some point in the future is no substitute for immediate review of the substantive and procedural lawfulness of the CMS Letter itself now.

The Administrative Procedures Act ("APA") provides for review of "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704 (2006). Congress intended the APA to cover a broad spectrum of administrative actions, and the Supreme Court has stated that the APA's "generous review provisions" must be given a "'hospitable' interpretation." *Bowen v. Massachusetts*, 487 U.S. 879, 904 (1988) (citing *Abbott Labs.*, 387 U.S. at 140-141). Indeed, there is a "strong presumption" that Congress intends to permit judicial review of administrative action, which may be overcome "only upon a showing of 'clear and convincing evidence' of a contrary legislative intent." *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 670–71 (1986); *Abbott Labs.*, 387 U.S. at 141. Relevant evidence includes "specific language or specific legislative history that is a reliable indicator of congressional intent, or a specific congressional intent to preclude judicial review that is fairly discernible in the detail of the legislative scheme." *Mich. Acad. of Family Physicians*, 476 U.S. at 673 (internal citations and quotations omitted).

Defendant's brief fails to identify any language in the SCHIP statute that explicitly forecloses judicial review; moreover, the narrow Court of Appeals review afforded under the SCHIP statute does not duplicate and, thus, implicitly foreclose, the type of action raised in this Complaint. *See generally Bowen v. Massachusetts*, 487 U.S. at 903 ("Congress did not intend the general grant of review in the APA to duplicate existing procedures for review of agency action."). The Court of Appeals review contemplated under the SCHIP statute is limited to challenges based on determinations regarding whether a state's SCHIP plan "conforms to the requirements for approval under [the relevant regulations]." 42 U.S.C. § 1316 (2006). It does

not address the allegations identified in this complaint, which consist of allegations that the agency's regulations, as set forth in the CMS Letter, constitute illegal rulemaking, are arbitrary and capricious, amount to an abuse of discretion, and are contrary to the Social Security Act and the regulations promulgated thereunder. *Compare id.* with Compl. ¶ 2. Courts will permit review of these types of "wholly collateral attacks" on a statute because otherwise, a "finding of preclusion [w]ould foreclose all meaningful judicial review." *Kreschollek v. Southern Stevedoring Co.*, 78 F.3d 868, 873 (3d Cir. 1996); *see also Leedom v. Kyne*, 358 U.S. 184, 190 (1958) (permitting review of otherwise unreviewable bargaining unit determination where petitioner alleged that agency exceeded its statutory authority).

Further, the remedy provided under the statute is inadequate to remedy the irreparable injury that will occur if New Jersey is forced to wait until it is deemed non-compliant, denied funding, and potentially sanctioned, before it can seek appellate court review under the statute. *See Kreschollek*, 78 F.3d at 875 (permitting review of plaintiff's constitutional claim that he was denied a pre-deprivation hearing because the administrative review scheme under the statute would be insufficient to provide him with the full relief to which he might be entitled).

C. Immediate Judicial Review is Especially Appropriate Where, as Here, the CMS Letter is in Direct Conflict with the Underlying Goals of SCHIP

The new rules established in the CMS Letter are in direct conflict with the underlying policy goals of SCHIP. The statute provides:

> The purpose of [SCHIP] is to provide funds to the States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage for children.

42 U.S.C. § 1397aa(a). The House Committee Report, prepared in support of an SCHIP predecessor,[2] further outlined the need for and the goals of an expanded children's health insurance program. *See* H.R. Rep. No. 105-149, at 602–03 (1997). The House explicitly recognized the need to provide states with discretion in the implementation of an expanded children's health insurance program. *Id*. at 621. Indeed, the House stated that "advances in the coverage of children have occurred when States have the flexibility to achieve maximum coverage through the Medicaid program and related initiatives." *Id*. at 603. These policies are made explicit in the implementing regulations, which state "within *broad* federal rules, *each State decides* eligible groups, types and ranges of services, payment levels for benefit coverage, and administrative and operating procedures." 42 C.F.R. § 457.1 (2007) (emphasis added). New Jersey has indeed exercised such discretion in ways that have effectively increased the number of children enrolled. It is such choices that are now being overturned by the CMS policy.

Moreover, the statutory framework of SCHIP provides further evidence that Congress intended to provide the states with broad discretion in the set-up and maintenance of their individual SCHIP programs. For example, states have the option of enrolling low-income children in an SCHIP-financed expansion of Medicaid, creating a new separate state SCHIP program, or devising a combination of these two approaches. 42 U.S.C. § 1397aa(a). The statute also grants the states flexibility in determining their individual plan eligibility requirements, allowing states to take into consideration a variety of factors, including geography, income and resources, residency, disability status, access to or coverage under other health insurance, and duration of eligibility. 42 U.S.C. § 1397bb(b)(1)(A) (2006). This type of state-

[2] The House of Representatives proposed a version of SCHIP known as the Child Health Assistance Program ("CHAP"), which is substantially similar to the SCHIP program that ultimately became law.

level flexibility was necessary to accomplish one of the goals of the program, which was to "provide the States with the tools they need to effectively provide needed services and expand Medicaid and private coverage to low-income uninsured children." H.R. Rep. No. 105-149, at 603.

Recognizing that each state faces a different set of health challenges, Congress intended to provide broad discretion to states like New Jersey to design a children's health insurance program that best suits its individual need. The CMS Letter eliminates the discretion previously afforded to New Jersey to adopt "reasonable procedures" to prevent substitution and crowd-out of public SCHIP coverage for private health insurance. *See* 42 C.F.R. § 457.805 (2007). In its place, the CMS Letter establishes stringent substitution benchmarks that are impossible to meet. In removing state-level discretion, CMS's new guidelines contravene the express Congressional policy of providing flexibility to the states to administer their individual SCHIP programs.

II. CMS ERRED AS A MATTER OF LAW BY ISSUING BINDING MANDATORY RULES WITHOUT FOLLOWING THE NOTICE AND COMMENT PROCEDURES REQUIRED BY THE APA

Contrary to Defendant's assertions, the new legislative rules governing SCHIP crowd-out and substitution strategies announced in the CMS Letter are neither interpretative rules nor general statements of policy. Instead, the CMS Letter is legislative in nature, and therefore must be submitted to notice and comment under the Administrative Procedure Act ("APA").

The APA requires an agency to provide notice of a proposed rulemaking and an opportunity for interested parties to comment prior to the rule's promulgation, amendment, modification, or repeal. 5 U.S.C. §§ 553(b)-(c) (2006); *Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1044 (D.C. Cir. 1987). The APA defines "rule" broadly to encompass virtually any statement that an agency could make, including statements "designed to implement, interpret, or

prescribe law or policy or describing the organization, procedure, or practice requirements of an agency . . ." 5 U.S.C. § 551(4) (2006); *Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 710 F.2d 842, 846 (D.C. Cir. 1983).

In limited circumstances, certain types of rules are exempt from the notice and comment requirements of the APA. Specifically, the APA exempts "interpretative rules" and "general statements of policy." 5 U.S.C. § 553(b) (2006). These exemptions, however, are narrowly construed; agencies must generally promulgate rules only after observing the notice and comment procedures. *Am. Hosp. Ass'n*, 834 F.2d at 1044–45.

A. The CMS Letter is Not An Interpretive Rule

As its name suggests, an interpretative rule seeks to *interpret* language already in properly issued law or regulations; that is, interpretative rules "merely clarify or explain existing law or regulations." *Reno-Sparks Indian Colony v. EPA*, 336 F.3d 899, 909 (9th Cir. 2003). Interpretative rules do not shift the rights or interests of the parties, although they may change the way in which the parties present themselves to the agency. *SBC Inc. v. Fed. Commc'ns Comm'n*, 414 F.3d 486, 498 (3d Cir. 2005) (citing *Chao v. Rothermel*, 327 F.3d 223, 227 (3d Cir. 2003)). An interpretative rule merely instructs as to what an agency thinks a statute or regulation means. *Reno-Sparks*, 336 F.3d at 909. In contrast, legislative rules, also known as substantive rules, are "those which effect a change in existing law or policy." *Id*. As noted above, interpretative rules are exempt from the notice and comment provisions of the APA, while legislative rules are not. *Chao*, 327 F.3d at 227.

The Third Circuit has identified several tests to determine whether a rule is legislative or interpretative. A rule is usually deemed to be legislative under following circumstances: it has a substantive adverse impact on the challenging party; it is used by anyone other than agency

employees; or, it represents a fundamental modification of a previous interpretation of a regulation. *Id*. at 227–28; *see also Mocanu v. Mueller*, 2008 WL 238443, at *2 n.7 (E.D. Pa. Jan. 25, 2008); *SBC Inc.*, 414 F.3d at 498 (citing *Paralyzed Veterans of Am. v. D.C. Arena, L.P.*, 117 F.3d 579, 586 (D.C. Cir. 1997)). These factors are all present in this case.

The CMS Letter has a substantive adverse impact on the state of New Jersey and its citizens. As described in detail above, the policies set forth in the CMS Letter will undermine the success the New Jersey SCHIP program has achieved and will render children uninsured. Second, the CMS Letter is intended to be used by – and controls the conduct of – non-agency employees, namely the state-level administrators who oversee state SCHIP programs. Finally, the CMS Letter represents a fundamental modification of a previous agency rule. Prior to the issuance of the CMS Letter, existing regulations provided that states broad discretion to implement "reasonable procedures" to prevent substitution of public SCHIP coverage for private coverage. 42 C.F.R. § 457.805.[3] The CMS Letter imposes new, specific crowd-out and substitution strategies, and does not explain or clarify what "reasonable procedures" means. The CMS Letter completely removes state-level discretion to determine what "reasonable procedures" are most appropriate for that individual state and imposes stringent requirements in its place. This is a fundamental modification of a prior legislative rule and must be subjected to notice and comment rulemaking. *Accord SBC Inc.*, 414 F.3d at 498; *cf. Paralyzed Veterans*, 117 F.3d at 588 ("If the statute or rule to be interpreted is itself very general, using terms like 'equitable' or 'fair,' and the 'interpretation' really provides all the guidance, then the latter will more likely be a substantive regulation.").

[3] Notably, HHS issued 42 C.F.R. § 457.805 after following the APA's notice and comment procedures. *See* Implementing Regulations for the State Children's Health Insurance Program, 66 Fed. Reg. 2490-01 (Jan. 11, 2001).

B. The CMS Letter is Not a General Statement of Policy

The CMS Letter is also not exempt from the notice and comment provisions of the APA as a general statement of policy because it establishes a new, binding legal norm related to crowd-out and substitution strategies for the state of New Jersey.

A general statement of policy is "merely an announcement to the public of the policy which the agency hopes to implement in future rulemakings or adjudications." *Panhandle Eastern Pipe Line Co. v. F.E.R.C.*, 198 F.3d 266, 269 (D.C. Cir. 1999). A general statement of policy does not establish a "binding norm," and it is not finally determinative of the issues or rights to which it is addressed. *Id.*; *see also Syncor Intern. Corp. v. Shalala*, 127 F.3d 90, 94 (D.C. Cir. 1997) ("The primary distinction between a substantive rule – really any rule – and a general statement of policy, then, turns on whether an agency intends to bind itself to a particular legal position") (internal citations omitted).

Unlike a mere announcement of a future agency policy, the CMS Letter establishes a binding legal norm with immediate and significant effects. As discussed in the previous section, the CMS Letter effectively replaces existing regulations, which allow a state to devise its own "reasonable procedures" to prevent substitution, with specific strategies and strict benchmarks related to crowd-out and substitution of private health insurance. The replacement of state-level discretion with these benchmarks "so fills out the statutory scheme" that upon application of the new rules, there is no question that New Jersey's current SCHIP plan will be rejected. *See Jean v. Nelson*, 711 F.2d 1455, 1481–82 (11th Cir. 1983). Further, there is absolutely no evidence in the record that CMS does not intend to bind itself to the rules announced in the CMS Letter. Indeed, the CMS Letter states that CMS "expects" states to act immediately to bring their SCHIP programs in line with the new rules. CMS Letter at 2. Far from a general statement of policy,

the CMS Letter establishes a binding legal norm and constitutes a legislative rule. Therefore, it must be subjected to notice and comment under the APA.

The CMS Letter will have a substantial impact on the state of New Jersey and it citizens, and will limit the availability of insurance for poor children in the state. The APA requires notice and comment rulemaking to ensure that substantive rules with immediate and significant impact, like those presented by this case, are thoroughly fleshed out and discussed in a public forum. *See also Dismas Charities, Inc. v. U.S. Dep't of Justice*, 401 F.3d 666, 678 (6th Cir. 2005) (explaining that "one of the central purposes of the requirement of notice and comment is to give those with interests affected by rules the chance to participate in the promulgation of the rules ... [in order to] ensure fair treatment for persons to be affected by regulations"). CMS's attempt to issue new legislative rules through an informal letter to state health officials amounts to nothing more than a clever attempt to "end-run" around the important protections afforded by the APA's notice and comment provisions. *See Sierra Club v. Tenn. Valley Auth.*, 430 F.3d 1337, 1349 (11th Cir. 2005).

III. CONCLUSION

The CMS Letter is an unlawfully promulgated binding rule that has an immediate and substantial impact on the State of New Jersey, its SCHIP plan, and the children insured under that plan. The issues raised by this suit are overwhelmingly legal, and the affected parties would benefit from immediate review. Accordingly, the *amici curiae* respectfully submit that the Court should exercise its jurisdiction to review the case and grant Plaintiff's Cross-Motion for Partial Summary Judgment.

Respectfully submitted,

Date: April 4, 2008

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CERTIFICATE OF SERVICE

I hereby certify that I have, this 4th day of April, 2008, caused a copy of the foregoing Joint Brief of *Amici Curiae* New Jersey Appleseed Public Interest Law Center et al. and the exhibits thereto to be served on the following individuals by United States Mail, first class postage prepaid, and by electronic means (if they are registered e-filers in this Court):

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