

June 3, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services (CMS)
U.S. Department of Health and Human Services
Attention: CMS-9115-P
Baltimore, MD. 21244-8016

The Honorable Don Rucker
Office of the National Coordinator for Health Information Technology (ONC)
U.S. Department of Health and Human Services
Attention: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT
Certification Program Proposed Rule
Mary E. Switzer Building, Email Stop: 7033A
330 C Street, SW., Washington, D.C. 20201

**RE: Behavioral IT Coalition Response to RIN 0955-AA01 & RIN 0938-AT79:
Stop Articulating New Health IT Standards Without New Resources**

Dear Administrator Verma and Dr. Rucker:

The undersigned members of the Behavioral Health Information Technology Coalition thank you the opportunity to respond to the combined CMS and ONC proposed interoperability and information blocking regulations.

The new proposed regulations address mental health and addiction treatment information technology (IT) issues in two (2) key areas: new Medicare Conditions of Participation (CoPs) for psychiatric hospitals and proposed Opioid Use Disorder (OUD) 2015 edition certification criteria in the form of a Request for Information (RFI).

In both instances, CMS and ONC articulate health IT standards without even hinting at the resources required to implement them. Indeed, ONC proposes to incorporate five (5) 2015 Certified EHR Technology (CEHRT) criteria into a “future non-binding information guide or resource...for OUD providers.” These proposals are without value and wholly inadequate to meet the challenges posed by the twin opioid use and mental health/suicide crises that are combining to reduce life expectancy in the United States. By contrast, to bring any sense of reality to the behavioral health IT standards contained in the interoperability and information blocking rules, funding should be set-aside in implementing Sec. 1003, Sec. 2005 and Sec. 6042 of the SUPPORT Act to enable mental health and addiction treatment providers to acquire certified EHR systems.

In our view, these objectives can be achieved through either of at least two alternatives:

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MEMBERS: American Psychological Association • Association for Behavioral Health and Wellness • Centerstone • Jewish Federations of North America • Mental Health America • National Alliance on Mental Illness • National Association of Counties • National Association of County Behavioral Health Directors & Developmental Disability Directors • National Association of Psychiatric Health Systems • National Association of State Alcohol/Drug Abuse Directors • National Association of Social Workers • National Council for Behavioral Health • Netsmart

1. CMS/the Center for Medicare and Medicaid Innovation (CMMI) should authorize higher reimbursement rates for mental health/addiction providers using EHR systems meeting 2015 ONC CERHT criteria or include performance-based lump sum incentives with the acquisition of health IT @ 2015 CERHT criteria as an authorized reimbursable expense.
2. Reserve a specific percentage of funds for all three (3) SUPPORT Act Medication Assisted Treatment (MAT) demonstrations for behavioral health providers to acquire or upgrade to 2015 CERHT.

MENTAL HEALTH AND ADDICTION TREATMENT HEALTH IT STANDARDS IN CMS/ONC INTEROPERABILITY & INFORMATION BLOCKING REGULATIONS

While RIN 0955-AAO1 and RIN 938-AT79 touch on several behavioral health issues, the rules articulate new health IT standards for two (2) sets of providers: psychiatric hospitals and Opioid Use Disorder (OUD) outpatient and inpatient treatment facilities. Although the regulations refer broadly to OUD “prevention and treatment,” the providers in this therapeutic space typically encompass: methadone clinics, residential treatment centers, specialty addiction doctors, psychologists, clinical social workers, and Community Mental Health Centers/Certified Community Behavioral Health Clinics (CCBHCs).

Sec. X.B./Sec. 482.61 – Condition of Participation: Special medical record requirements for psychiatric hospitals

What Are the New Psychiatric Hospital Health IT Medicare Conditions of Participation (CoPs)?

On pages 241 and 242 of RIN 0938-AT79/CMS-9115-P, new Medicare Conditions of Participation (CoPs) are proposed for psychiatric hospitals. The preamble beginning on pg. 152 goes into greater depth. CMS recommends that inpatient psychiatric facilities generate Admission, Discharge and Transfer (ADT) electronic patient event notifications. Through exchange standards incorporated in federal regulations (45 CFR 170.299(f)(2)), these hospitals would be required to send notifications that, at minimum, include patient health information, treating practitioner name, institution name, and patient diagnosis to “licensed and qualified practitioners” who meet loosely-defined guidelines outlined on pg. 153. Like electronic ADT notifications proposed for medical/surgical hospitals, the rule applies this new health IT requirement only to psychiatric hospitals “which currently possess EHR systems” capable of meeting the technical specifications required in RIN 0938-AT79/CMS-9115-P.

BHIT Coalition Response: With proper additional resources, the new health IT requirements described in Sec. 482.61 above could significantly advance care coordination and continuity of care for these highly vulnerable patients. “People with severe mental illnesses (SMI), including schizophrenia, bipolar disorder and major clinical depression, as well as persons with OUD, are heavy utilizers of community hospital emergency departments (ED) and are at high risk of readmission to both medical/surgical hospitals and

inpatient psychiatric facilities¹". In turn, this utilization pattern is driven by drug overdoses and a broad range of psychiatric emergencies, including psychotic episodes and/or suicidal ideation typically associated with major clinical depression. It is little understood that high ED use also results from poorly managed chronic diseases in these same patient populations who experience a strikingly "high prevalence of co-occurring HIV/AIDS, Hepatitis C, cirrhosis, emphysema, diabetes and heart disease²".

Two recent studies confirm these assertions:

In Oct 2018, a research article entitled, *Factors Associated with Emergency Department Use by Patients With and Without Mental Health Diagnoses*, published in the Journal of the American Medical Association (JAMA) Open Network, took a rigorous approach to investigating ED utilization³. The researchers examined all ED visits at licensed hospitals in California between 2012 and 2014. Here are the highlights:

- "Approximately 50% of frequent ED users have a mental health diagnosis, and this group has higher rates of morbidity and mortality and incurs higher costs over time." (pg. 2)
- "Additionally, frequent ED users often have many issues that historically have been considered nonmedical including.....addiction." (pg. 2)
- "Combined, a patient with a primary mental health diagnosis and a severe mental health diagnosis...like schizophrenia...would be predicted to have more than 2 times as many visits compared to patients without any mental health diagnosis." (pg. 8)

The new proposed Medicare behavioral health IT requirement for inpatient psychiatric hospitals seeks to address a key problem highlighted in the JAMA article: "Continuity and coordination of care critical for effective mental health care is lacking in public health delivery systems⁴" (pg. 9).

In January 2019, Premier...a nationwide hospital system...released a study estimating that patients experiencing opioid overdoses resulted in nearly \$2 billion of annual hospital costs across 647 healthcare facilities and \$11.3 billion annually to the larger U.S. health care system⁵. Some highlights:

- "Opioid overdose patients that present to the ED are at high risk of multiple organ failure, hospitalization, increased costs due to ICU stays and unplanned readmissions following discharge."
- "The average cost for an overdose patient who was treated and released totaled \$504, but the average cost rose to \$11,731 for those that were treated and admitted and up to \$20,500 for those that required ICU care."
- "Moreover, of those who are treated and released from the ED, about 24% were readmitted for additional emergency care within 30 days of discharge."

¹Niedzwiecki MJ, Sharma PJ, Kanzaria HK, McConville S, Hsia RY. Factors Associated With Emergency Department Use by Patients With and Without Mental Health Diagnoses. *JAMA Network Open*.2018;1(6):e183528. doi:10.1001/jamanetworkopen.2018.3528

² Neumark, Y.D., M.L. Van Etten, and J.C. Anthony, "Alcohol dependence" and death: survival analysis of the Baltimore ECA sample from 1981 to 1995. *Substance use & misuse*, 2000. 35(4): p. 533-549

³ Niedzwiecki MJ, Sharma PJ, Kanzaria HK, McConville S, Hsia RY. Factors Associated With Emergency Department Use by Patients With and Without Mental Health Diagnoses. *JAMA Network Open*.2018;1(6):e183528. doi:10.1001/jamanetworkopen.2018.3528

⁴ Niedzwiecki MJ, Sharma PJ, Kanzaria HK, McConville S, Hsia RY. Factors Associated With Emergency Department Use by Patients With and Without Mental Health Diagnoses. *JAMA Network Open*.2018;1(6):e183528. doi:10.1001/jamanetworkopen.2018.3528

⁵ Premier, Inc. (2018, January 3). Opioid Overdoses Costing U.S. Hospitals an Estimated \$11 Billion... Retrieved from <https://www.premierinc.com/newsroom/press-releases/opioid-overdoses-costing-u-s-hospitals-an-estimated-11-billion-annually>

But while data on the need to sustain continuity of care for these patients across treatment settings is compelling, the CMS electronic ADT event notification requirement divorced from day-to-day reality. Because the original drafters of the HITECH Act mistakenly classified patients with serious mental health and addiction disorders as “post-acute,” the vast majority of behavioral health providers maintain paper medical records and exchange patient data via fax.

Relative to psychiatric hospitals specifically, the National Association for Behavioral Health commissioned Manatt Health to produce a report published in March 2019 entitled, *The High Cost of Compliance: Assessing the Regulatory Burden on Inpatient Psychiatric Facilities*⁶. In turn, the report made a specific reference to health IT issues:

“Because of these B-tag interpretations, clinicians must spend time crafting highly tailored free-text plans and progress notes. Often, these documents must be written out by hand because many freestanding psychiatric hospitals do not have electronic health records (in part, because they were excluded from the \$38 billion Incentive Program that CMS established in 2011). This approach is out of step not only with standard practice in non-psychiatric disciplines, but also with the medical industry’s trend toward appropriate use of check boxes and standardized language, which saves clinicians time and which (when contained in an electronic record) makes the data more searchable, analyzable, and portable.”

In short, the proposed CMS electronic ADT event notification requirement imposed on inpatient psychiatric hospitals through new Medicare CoPs is unrealistic and unfair without also including additional resources to help these providers obtain modern health IT systems.

Sec. VI. Health IT for the Care Continuum/B. Health IT Opioid Use Disorder Prevention and Treatment

Beginning on pg. 143 of the preamble for RIN 0955-AA01, there is a lengthy discussion about the “need to explore ways to advance health IT across the care continuum to support efforts to fight the opioid epidemic.” Further, the ONC includes a Request for Information (RFI) on the application of several 2015 Edition certification criteria available now which could “support care coordination and the prevention and detection of opioid misuse, abuse and diversion.”

What follows constitutes the BHIT Coalition’s formal response to the ONC RFI.

What Are the Proposed OUD Health IT Standards? On pages 147 and 148 of the preamble, ONC proposes to apply 2015 Edition CERHT criteria to the “care coordination and the prevention and detection of opioid misuse, abuse, and adverse events.” The BHIT Coalition is uncertain whether ONC deliberately omitted addiction treatment or whether the omission was in error. In any event, the agency proposes applying the following five (5) health IT standards to the opioid therapeutic space:

⁶ N. (2019, March 19). The High Cost of Compliance: Assessing the Regulatory Burden on Inpatient Psychiatric Facilities. Retrieved from <https://www.nabh.org/nabh-releases-the-high-cost-of-compliance-assessing-the-regulatory-burden-on-inpatient-psychiatric-facilities/>

- Transitions of care criterion (170.315(b)(1))
- Clinical information reconciliation and incorporation criterion (170.315(b)(2))
- Electronic prescribing criterion (170.315(b)(3))
- Patient health information capture (170.315(e)(3))
- Social, psychological and behavioral data criteria (170.315(a) (15))

These criteria would have significant value when applied to Medication Assisted Treatment (MAT)⁷ – specifically among clinicians prescribing buprenorphine/Suboxone. This oral medication, which can be prescribed on an outpatient basis by physicians and filled in most pharmacies nationwide, is a key component of broader efforts by the Trump Administration, states, counties and cities to expand access to substance use services in rural areas and underserved communities. As HHS Secretary Azar has noted on several occasions, MAT is the “gold standard” of addiction medicine.

At the same time, like other FDA-approved oral medications, buprenorphine contraindicates with other pharmaceutical agents⁸. For example, buprenorphine contraindicates with Xanax and its entire class of widely prescribed benzodiazepines, as well as other opioids including analgesic products like Vicodin or OxyContin.

Moreover, both methadone and buprenorphine are controlled substances subject to diversion. Estimates of buprenorphine diversion vary both in the United States and internationally. Most recently, the Drug Enforcement Administration (DEA) asserted that the prescription diversion rate for “buprenorphine-containing drugs” is 95%⁹; other entities have estimated much lower rates. DEA also alleges that providers evade detection by mislabeling prescriptions for pain management. “Patients are known to divide tablets, potentially making it easier to smuggle than tablets; its individual packaging makes it more portable for reselling and sharing; and serial numbers on packaging are not electronically tracked and not shown to deter diversion¹⁰”.

BHIT Coalition Responses to OUD RFI: In the view of the BHIT Coalition, the ONC e-prescribing criterion – assuming the agency means to apply it to MAT – would likely be highly effective in averting diversion.

Further, the clinical information reconciliation and incorporation criterion would help ensure that buprenorphine can be prescribed safely.

⁷ Wilford, B. B., Kelly, M. A., & Hylton, R. D. (2019). Supplement To The Final Summary Report From The SAMHSA Evaluation Of The Buprenorphine Waiver Program: An Updated Literature Review. Retrieved from https://www.samhsa.gov/sites/default/files/programs_campaigns/medication_assisted/buprenorphine-waiver-program-literature-review.pdf

⁸ “Suboxone Drug Interactions.” *Drugs.com*, Drugs.com, www.drugs.com/drug-interactions/buprenorphine-nalaxone,suboxone.html.

⁹ USA vs. INDIVIOR INC., 30 (United States District Court Western District of Virginia Abingdon April 9, 2019).

¹⁰ USA vs. INDIVIOR INC., 9 (United States District Court Western District of Virginia Abingdon April 9, 2019).

Given the incidence of HIV/AIDS, Hepatitis C, and co-occurring chronic medical conditions among persons with OUD, the transition of care criterion could strengthen the clinical management of these patients across the behavioral health and medical/surgical continuums of care.

But RIN 0995-AA01 simultaneously sacrifices all of these clinical advantages by suggesting that the five (5) 2015 Edition CEHRT criteria should be rolled into “a potential future non-binding informational guide or resource to provide... information for OUD providers and sites of services related to specific clinical priorities and use cases of focus.”

Whatever the value of this recommendation is, it utterly fails to address fundamental realities. One recent survey documented that although “97% of medical/surgical hospitals and 74% of physicians have implemented EHR systems, fewer than 30% of behavioral health provider have done so”^{11,12}. Specifically, roughly 10% of psychiatric hospitals and about 25% of Community Mental Health Centers use 2015 edition systems guided by 2015 ONC certification standards. The health IT penetration rate for addiction treatment providers... e.g. methadone clinics, residential treatment facilities, outpatient substance use providers...is likely lower. *Given these circumstances, enunciating new behavioral IT standards in the absence of additional resources is without clinical merit.*

CONCLUSION – CMS/ONC NEED TO TAKE TWO KEY STEPS

In addition to modifications to the interoperability and information blocking rules, the BHIT Coalition recommends that ONC and CMS partner to take two key actions to address the twin mental health and opioid crises.

First, these agencies should make a declaration – published in the *Federal Register* – that persons with severe mental health and Opioid Use Disorders are not “post-acute care populations” for the purposes of implementing what is now called the ONC Promoting Interoperability Program. This step should be simple recognition of the obvious. “Researchers have shown that people with substance use disorders die as much as 20 years earlier than other Americans – primarily from co-morbid chronic diseases including cancer, cardiovascular disorders, HIV/AIDS and a host of other illnesses¹³”. The Centers for Disease Control and Prevention (CDC) reported that more than 70,000 persons in the U.S. lost their lives to drug overdoses in 2017. Similarly, most Americans with SMI experience early mortality and don’t live beyond their 53rd birthday.

¹¹ P. Ranallo, A. M. Kilbourne, A.S. Whatley et al., “Behavioral Health Information Technology: From Chaos to Clarity,” *Health Affairs*, June 2016 35(6):1106-13

¹² Caviness, C. M., Anderson, B. J., de Dios, M. A., Kurth, M., & Stein, M. (2013). *Prescription Medication Exchange Patterns Among Methadone Maintenance Patients*. *Drug and Alcohol Dependence*, 127(1-3), 232-238. <http://doi.org/10.1016/j.drugalcdep.2012.01.007>

¹³ Neumark, Y.D., M.L. Van Etten, and J.C. Anthony, “*Alcohol dependence and death: survival analysis of the Baltimore ECA sample from 1981 to 1995*.” *Substance use & misuse*, 2000. 35(4): p. 533-549

Second, we recommend that ONC and CMS partner to apply the five (5) 2015 Edition CEHRT criteria identified in the OUD RFI to the three (3) pending SUPPORT Act CMMI MAT demonstrations, while simultaneously incorporating funding for behavioral health and addiction treatment providers to acquire or update to current health IT technology. The BHIT Coalition refers specifically to the CMMI demonstration authorized under Section 6042 of the SUPPORT Act (PL 115-271), the Medicare Opioid Treatment Programs bundled payment program authorized under Section 2005 of the SUPPORT Act, and the Medicaid provider infrastructure demonstration authorized under Section 1003 of the SUPPORT Act.

Within these three demonstrations, higher reimbursement rates or higher performance based lump sum payments would be made to behavioral health providers using EHR systems meeting 2015 ONC CERHT standards specifically tied to the five (5) criteria identified in the OUD RFI. Finally, the eligible universe of providers would be those identified in Section 6001 of the SUPPORT Act: psychiatric hospitals, Community Mental Health Centers/CCBHCs, psychologists, clinical workers and addiction treatment providers, including methadone clinics, residential treatment centers and addiction doctors participating in Medicaid OUD emergency waiver programs

In sum, the BHIT Coalition proposal would have much greater impact on patients now confronting life-threatening medical conditions than a “non-binding informational guide.”

Thank you for your willingness to consider our views.

Sincerely,

American Psychological Association

Centerstone

The Jewish Federations of North America

Mental Health America

National Alliance on Mental Illness

National Association for Behavioral Healthcare

National Association of Counties

The National Association of County Behavioral Health and Developmental Disability Directors

The National Association for Rural Mental Health

National Association of Social Workers

National Council for Behavioral Health

Netsmart