



April 11, 2016

The Substance Abuse and Mental Health Services Administration
Department of Health and Human Services
Attn: SAMHSA-4162-20
5600 Fishers Lane
Room 13N02B
Rockville, MD 20852

On behalf of AMGA, we appreciate the opportunity to comment on the Substance Abuse and Mental Health Services Administration's (SAMHSA) "Confidentiality of Substance Use Disorder Patient Records" proposed rule. AMGA, founded in 1950, represents more than 450 multi-specialty medical groups and integrated delivery systems representing about 177,000 physicians who care for one-in-three Americans. Our member medical groups participate in a wide array of integrated health care models, such as the Medicare Shared Savings Program (MSSP), or the Accountable Care Organization (ACO) program, as well as in the Pioneer and Next Generation ACO demonstrations. AMGA, therefore, has a strong interest in the proposed changes to 42 CFR Part 2, as these changes will help substance abuse patients be able to participate more fully in and benefit from integrated care delivery.

The proposed rule intends to update Title 42 of the CFR part 2 first promulgated in 1975 and last substantively updated in 1987. Generally, the proposed rule is intended to accomplish or address several goals. SAMHSA argues in part, "Modernization is necessary because behavioral health, including substance use disorder treatment, is essential to overall health; the costs of untreated substance use disorders, both personal and societal, are substantial." The proposed rule is intended to "modernize the 42 CFR part 2 rules by facilitating the electronic exchange of substance use disorder information for treatment and other legitimate health care purposes while ensuring appropriate confidentiality protections for records that might identify the individual, directly or indirectly, as having or having had a substance use disorder." More specifically, the proposed rule is intended to "increase opportunities for individuals with substance use disorders to participate in new and emerging health and health care models and health information technology. Our intent is to facilitate the sharing of information within the health care system to support new models of integrated health care which, among other things, improve patient safety while maintaining or strengthening privacy protections for individuals seeking treatment for substance use disorders." The rule applies to patient identifying information generated by federally assisted substance use disorder treatment programs or entities that provide alcohol or drug abuse diagnosis, treatment, or referral for treatment. Broadly, this means any program participating in Medicare. The proposed rule also revises eleven existing definitions and adds five new definitions.

AMGA supports SAMHSA's efforts to update 42 CFR part 2 for several reasons. Substance abuse

affects one in 11 Americans older than 11. According to the Centers for Disease Control and Prevention, the U.S. is "experiencing an epidemic of drug overdose (poisoning) deaths." Substance abuse deaths associated with drug overdose alone accounted for more than 47,000 deaths in 2014. That is more deaths than any previous year on record and one and a half times more than those caused by motor vehicle crashes. Overdose deaths specifically associated with opioids (opioid pain relievers and heroin) have increased by 200% since 2000.¹ For patient safety related issues alone, AMGA believes updating 42 CFR part 2 to improve substance abuse patient participation in, and benefit from, integrated care networks justifies finalizing the proposed rule.

Inclusion of General Medical Practices and Qualified Service Organizations (QSOs)

SAMHSA proposes to include "general medical facilities" and "general medical practices" if these hold themselves out as providing and provides substance use disorder diagnosis, treatment, or referral for treatment.

Including Population Health Management Services By a Qualified Service Organizations

SAMHSA proposes to include population health management in the list of examples of services a Qualified Service Organizations (QSO) may provide. Under a QSO agreement between a part 2 provider and an organization, providing population health management would be limited to the office or unit responsible for the population health management in the organization, not the entire organization. AMGA agrees with this proposal.

"To Whom" Consent

Under certain circumstances SAMHSA proposes to permit the inclusion "of a general designation in the "To Whom" section of the consent form." SAMHSA is proposing to "permit the designation of name/s of entity/ies and a general description of an individual or entity participant/s or a class of participants" that have a "treating provider relationship with the patient whose information is being disclosed. The consent form could designate a Health Information Exchange (HIE) but the HIE would have to be the specified HIE used by the treating provider. "Merely listing a function is not sufficient for consent because it would not sufficiently identify the recipient of the patient identifying information." AMGA agrees with this approach. We appreciate SAMHSA's statement, "Because SAMHSA wants to ensure that patient identifying information is only disclosed to those individuals and entities on the health care team with a need to know this sensitive information, we are limiting a general designation to those individuals or entities with a treating provider relationship."

List of Disclosures

By allowing for a "general designation", or to "balance the flexibility afforded by the general designation in the "To Whom" section," SAMHSA proposes to add a "new confidentiality safeguard: List of Disclosures." Because the substance abuse patient could allow a "general designation," SAMHSA is proposing "the entity without a treating provider relationship" provide "a list of entities to which their information has been disclosed per the general designation" and these can include individual names. SAMHSA states further "individuals who receive patient identifying information pursuant to the general designation on the consent form should be included on the List of Disclosures based on an entity affiliation." However, SAMHSA concludes "patients who wish to know the name of the individual to whom their information was disclosed may ask the entity on the List of Disclosures to provide that information, however, 42 CFR part 2 would not require the entity to comply with the patient's request." The absence of requiring disclosure of individual names undermines the intent of the List of Disclosures and undermines the purpose of expanding the "To Whom" provision and the patient's incentive or willingness to consent to a "general designation."

For various reasons, SAMHSA proposes the List of Disclosures requirement not become effective until two years after the effective date of the final part 2 rule. AMGA well recognizes revising 42 CFR part 2 is long overdue. Regardless, expanding "To Whom" consent without patients having the ability to request "disclosure" for two years is problematic; the patient is effectively asked to blindly consent to wide disclosure of their substance use records. Making the requisite clerical and information technical modifications is not a two year exercise. AMGA recommends that SAMSHA implement the List of Disclosures requirement within 90 days.

Consent Requirements

AMGA supports SAMHSA's proposal "to require a part 2 program or other lawful holder of patient identifying information to obtain written confirmation from the patient that they understand the terms of their consent and, when using a general designation in the "To Whom" section of the consent form . . . that they have the right to obtain, upon request, a list of entities to which their information has been disclosed pursuant to the general designation."

Research Provisions

SAMHSA proposes to permit part 2 protected data to be disclosed to "qualified personnel for the purpose of conducting scientific research by a part 2 program." These "lawful holders of part 2 data could include third-party payers" such as "HIEs, ACOs, and CCOS [Coordinated Care Organizations]." AMGA supports this proposal. AMGA also supports SAMHSA's proposal to allow "patient identifying information to be disclosed for purposes of scientific research" under the two conditions outlined and AMGA supports the proposal to permit "researchers to request to link data sets" under the two conditions specified and to "limit the data repositories from which a researcher may request data for data linkages purposes to federal data repositories" as explained.

The proposed rule, along with SAMHSA's September 2015 Common Rule proposed rule, appears silent on the issue of researcher access to Medicare or Medicaid claim data that includes substance use disorder diagnoses or related procedural codes. In a December 2015 Research Data Assistance Center (ResDAC) memo, the Centers for Medicare and Medicaid Services (CMS) wrote, "Therefore, to ensure compliance with SAMHSA regulations, after gathering requested data for a researcher, CMS redacts any substance abuse related claims from the resulting research identifiable files based on codes within the claims." CMS admits, for example, the agency suppressed claims accounts for 20% of all "aged" Medicaid claims.² Since substance abuse documentation is present in a substantial percent of federal medical claims data, making these records unavailable compromises researchers' ability to study substance use care as well as providers' ability to treat these patients and develop better, more effective treatment protocols. This problem has been widely discussed in The New England Journal of Medicine and elsewhere.³ We strongly encourage SAMHSA to clarify in the final rule CMS's interpretation of SAMHSA's "Confidentiality of Alcohol and Drug Abuse Patient Records Regulation." Further still, we encourage SAMHSA to identify a pathway in which these records can be made responsibly available.

Medical Emergencies

SAMHSA proposes to "adapt the medical emergency exception to give providers more discretion to determine when a "bona fide medical emergency . . . exists." That is a patient's identifying information may be disclosed to medical personnel "to the extent necessary to meet a bona fide medical emergency, to which the patients prior informed consent cannot be obtained." SAMHSA "proposes to continue to require the part 2 program to document immediately, in writing, specific information related to the medical emergency." In addition, SAMHSA states a part 2 program before entering into an affiliation

with an HIE, "consider whether the HIE has the capability to comply with all part 2 requirements, including the capacity to immediately notify the part 2 program when its records have been disclosed pursuant to a medical emergency." Since substance use patients commonly face medical emergencies, and, for example, require the use of emergency department care, it appears prudent an emergency department/s be named or identified under the "general disclosure" provision.

Prescription Drug Monitoring Programs (PDMPs)

SAMHSA recognizes the proposed rule does not address "issues pertaining to e-prescribing and Physician Drug Monitoring Programs (PDMPs). SAMHSA states these topics are "not ripe for rulemaking at this time due to the state of technology and because the majority of part 2 programs are not prescribing controlled substances electronically." Though we offer no evidence, our experience tells us it is difficult to believe many multi-specialty, integrated care providers are not e-prescribing, or not required or incented, to e-prescribe controlled substances and/or are not formally monitoring these drug prescriptions. In the final rule it would be useful for the Administration to provide e-prescribing and PDMP-related data.

Estimated Costs

SAMHSA estimates implementation costs for the proposed include updates to health information technology systems, costs for staff training and staff training curricula, updates to training curriculum, costs to update patient consent forms, costs associated with providing patients a list of entities to which their information has been disclosed, and implementation costs associated with the List of Disclosure requirements. SAMHSA estimates total costs at \$239 million over ten years or through 2024. We do not believe these costs are unduly burdensome, rather these changes improve patient care and again moreover patient safety and enable substance use disorder patients to participate in and benefit from integrated care delivery models.

Thank you for your careful consideration of our comments. AMGA is happy to discuss these further. Please contact David Introcaso, Ph.D., Senior Director, Regulatory and Public Policy at 703.838.0033, extension 335, with any questions.

Sincerely,



Donald W. Fisher, Ph.D.
President and CEO

Endnotes

1. Rose A. Rudd, et al., "Increases in Drug and Opioid Overdose Deaths - United States, 2000-2014," *Morbidity and Mortality Weekly Report* (January 1, 2016). At: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm>.
2. ResDAC, "Redaction of Substance Abuse Claims," (December 16, 2015). At: <http://www.resdac.org/resconnect/articles/203>. See also at the bottom of this page the link to the table titled, "Statistics: Impact of Redaction of Medicare and Medicaid Claims."
3. Austin B. Frakt and Nicholas Bagley, "Protection or Harm? Suppressing Substance-Use Data," *The New England Journal of Medicine* (April 15, 2015). At: <http://www.nejm.org/doi/full/10.1056/NEJMp1501362>.