October 25, 2019

The Honorable Elinore F. McCance-Katz, M.D., Ph.D.
Assistant Secretary for Mental Health and Substance Use
Substance Abuse and Mental Health Services Administration
Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

RE: Confidentiality of Substance Abuse Disorder Patient Records

RIN: 0930-AA32

Dear Assistant Secretary McCance-Katz:

The Medical Group Management Association (MGMA) is pleased to submit the following response to the Substance Abuse and Mental Health Services Administration (SAMHSA) Proposed Rule, *Confidentiality of Substance Abuse Disorder Patient Records.* We appreciate the agency's efforts to address the nation's opioid epidemic and improve care coordination for individuals with a substance use disorder (SUD). Ensuring that clinicians have access to pertinent patient information is vital to the treatment process. However, how patient medical records are shared under 42 CFR Part 2 (Part 2) can significantly increase the chance of inappropriate access and the potential of patient discrimination. The regulatory environment should be structured to encourage patients to share their information with trusted care partners while not serving as a barrier to those seeking SUD treatment.

MGMA is the premier association for professionals who lead medical practices. Since 1926, through data, people, insights, and advocacy, MGMA empowers medical group practices to innovate and create meaningful change in healthcare. With a membership of more than 55,000 medical practice administrators, executives, and leaders, MGMA represents more than 15,000 organizations of all sizes, types, structures and specialties that deliver almost half of the healthcare in the United States.

MGMA urges caution regarding efforts to ease the disclosure of sensitive patient information. There remains a great lack of education and training among medical and legal professionals regarding SUD and even more so regarding the requirements for sharing such sensitive patient information. According to a recent SAMHSA report, the vast majority of individuals needing treatment do not seek treatment. We are concerned that inappropriate relaxation of Part 2 requirements could have a negative impact on the number of individuals seeking SUD treatment and hinder the openness necessary during the physician-patient discussion to appropriately treat an individual.

Those seeking to modify Part 2 should consider the following in any broader reform effort: (i) regulations must permit clients/patients with SUD the right to give affirmative consent for their records to be shared with any other physician or care setting for treatment, payment, or health-care operations; these rights should include the specific information to be shared, with whom specifically, and the time constraints of the release of information; (ii) regulations must permit SUD clients/patients the right to give consent each time their medical record is shared with a

clinician outside the health system that originally treated them for substance use; and (iii) priority must be given to provider and patient education and training on the use of Part 2 restrictions and requirements.

Specific Comments on the Regulation

SAMHSA Proposal (pg. 44574)

Therefore, SAMHSA proposes to amend the current regulations to clarify that patients may consent to disclosures of part 2 information to organizations without a treating provider relationship. We propose to amend § 42 CFR 2.31(a)(4)(i), which currently requires a written consent to include the names of individual(s) to whom a disclosure is to be made. The amendment would insert the words ''or the name(s) of the entity(- ies)'' to that section, so that a written consent must include the name(s) of the individual(s) or entity(-ies) to whom or to which a disclosure is to be made…As stated in the January 2017 final rule (82 FR 6084), for entities that facilitate the exchange of health information or are research institutions, 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. Therefore, in instances where information is disclosed to entities that facilitate the exchange of health information or research institutions, SAMHSA will continue to limit the ability to use a general designation (e.g., ''all my treating providers'') in the ''to whom'' section of the consent requirements to those individuals or entities with a treating provider relationship.

MGMA Comment

Under current regulation, if the physician practice does not have a treating provider relationship with the patient whose information is being disclosed and is not a third-party payer, such as an entity that facilitates the exchange of healthcare information or research institutions, the written consent must include the name of the entity and one of the following: ''the name(s) of an individual participant(s); the name(s) of an entity participant(s) that has a treating provider relationship with the patient whose information is being disclosed; or a general designation of an individual or entity participant(s) or class of participants that must be limited to a participant(s) who has a treating provider relationship with the patient whose information is being disclosed.''

MGMA supports SAMHSA's proposed clarification that patients may consent to disclosures of Part 2 information to individuals or entities. We also recommend adding regulatory language to specify that patients may consent to permit both their Part 2 facility and health information exchange networks of their choosing to disclose their health information to past, present, and future treating providers. We also agree with the proposed rule's continuing requirement to limit the ability to use a general designation in the 'to whom' section of the consent requirements to those individuals or entities with a treating provider relationship to the patient at issue.

We also concur with the agency's recognition that SUD patients can benefit from receiving assistance from community-based programs. Requiring the patient to name a specific individual employed at a program to be authorized to receive a patient's SUD information could make it more challenging for the patient to receive the services. Further, the group practice model is such that treatment may be offered to a patient using a "team-based" approached and thus the patient may not know the name of a specific provider. We concur with SAMHSA that patient-identifying information should only be disclosed to those individuals and entities on the care team who need to know this sensitive information. Overall, we applaud the agency's effort to create a consent process that is not overly onerous to patients or their treating clinicians.

SAMHSA Proposal (pg. 44577)

SAMHSA believes that permitting part 2 programs, including OTPs, and lawful holders to enroll in PDMPs and submit the dispensing data for controlled substances required by states currently for other prescribed, controlled substances would allow for greater patient safety, better patient treatment, and better care coordination among the patient's providers. Therefore, SAMHSA proposes to add a new section § 2.36, permitting OTPs and other lawful holders to report the required data to their respective state PDMPs when dispensing medications. The proposed rule would require part 2 providers to obtain written consent from the patient whose identifying information will be disclosed prior to making such reports.

MGMA Comment

One of the tools most critically underutilized in the fight against the opioid epidemic is e-prescribing. E-prescribing of opioids will allow providers to flag potential overuse or misuse for patients more easily when prescribed by multiple providers through real-time notifications. It would also facilitate the collection of data that could be studied and used to inform ongoing efforts to curb opioid overuse and misuse.

For maximum effectiveness, efforts to incentivize e-prescribing should be coupled with efforts to promote a nationally accessible Prescription Drug Monitoring Program (PDMP). Currently, 45 states participate in the National Association of Boards of Pharmacy's (NABP's) prescription monitoring program (PMP) and data sharing program. This type of federated model allows states to retain control over their own databases while granting access to appropriately authorized clinicians in other regions. This enables more effective treatment decisions and closes the loophole that exists when addicted patients seek new prescriptions across state lines. All remaining states should be encouraged to join this broad effort to communicate prescription information.

In addition, integration of this data into EHRs should ensure that the clinician has access to the data during the time of the patient encounter. Currently, some EHR PDMP interfaces permit the clinician to access various state PDMPs, but typically each state must be accessed individually -- meaning it is burdensome for the clinician to search a patient's prescribing history in multiple states before or during the encounter. A more effective approach would be to have the patient's PDMP records automatically combined from each state and presented to the clinician in an easy-to-read format and available in real-time. This would allow the clinician to engage with the patient during the encounter and take appropriate prescribing actions.

We agree that federal agencies, in partnership with states, should improve interoperability between health IT and PDMPs through the adoption of common industry standards consistent with federal policies and the HIPAA Privacy and Security Rules. This would improve timely access for clinicians to medication histories in PDMPs. States should also leverage funding sources, including but not limited to 100 percent federal Medicaid financing under the 2018 SUPPORT for Patients and Communities Act (SUPPORT Act), to facilitate EHR integration with PDMPs using existing standards.

Accessing prescription histories from PDMPs is typically not well integrated into the routine workflow of patient care or even the e-prescribing workflow. If we are to effectively combat the opioid crisis facing this nation, clinicians require efficient and rapid access to data from all state PDMPs. The SUPPORT Act now allows states to receive 100 percent federal Medicaid matching funds in 2019-2020 for qualified PDMPs that integrate into a provider's workflow and their health IT application for e-prescribing of controlled substances. We urge, in implementing the SUPPORT Act, the federal government to coordinate the applicable agencies to develop a shared strategy to

ensure that all PDMPs adopt common standards over time to support PDMP and health IT integration.

HHS, for example, should look at various policy levers to promote the e-prescribing of controlled substances with access to medication history. One would be to include e-prescribing of controlled substances as one of the scoreable MIPS Improvement activities. A second option would be to require future Certified EHR Technology editions to include these functionalities. We agree that, when appropriately implemented, e-prescribing of controlled substances will permit all prescribing to remain in a single workflow, reduce the time clinicians spend on medication reconciliation, automate clinical decision support such as drug-drug interactions, and facilitate the tracking of prescription fulfillment. As the SUPPORT Act also requires the Drug Enforcement Agency to update clinician multifactor authentication requirements to leverage biometrics and modern approaches to authentication, we recommend ensuring that the solutions developed are clinician-friendly and seamlessly integrated into provider workflows.

In addition, MGMA has significant concerns regarding the ability of law enforcement or other non-healthcare actors to access PDMP data. PDMP data not only includes SUD history but also other types of sensitive information such as HIV/AIDS that could be the subject of discrimination against a patient. PDMPs are typically not subject to federal or state privacy laws that protect personal health information and, as of August 2018, 34 states permit law enforcement agencies to perform unlimited PDMP searches on any individual as long as there is an active investigation open. The agency's recognition that this practice exists—"PDMPs operated by law enforcement agencies are already receiving some patient data related to SUD treatment" (page 44577)—is not an acceptable justification for permitting this practice.

Furthermore, expanding access to PDMP data is not needed to accomplish SAMHSA's intended goal. Patients continue to have the ability to provide consent to release prescription history directly to their treating provider, central registry, or health information exchange, with each having significantly stronger patient privacy protections than PDMPs currently have. Thus, absent the inclusion of additional privacy protections to safeguard patient information in PDMPs from disclosure or re-disclosure to non-health care professionals, MGMA opposes SAMHSA's proposal.

SAMHSA Proposal (pg. 44577)

Specifically, SAMHSA proposes that this medical emergency exception would apply only when a state or federal authority declares a state of emergency as a result of a disaster and the part 2 program is closed and unable to provide services or obtain the informed consent of the patient as a result of the disaster, and would immediately be rescinded once the part 2 program resumes operations.

MGMA Comment

When access to, or operation of, substance use disorder treatment facilities and services are disrupted on a regional basis in the wake of a disaster like a hurricane or wildfire, many patients become unable to access care through their usual providers, while many physician practices may be unable to follow usual consent-based procedures in order to obtain and/or release records for large numbers of patients. Thus, the disclosure requirements of Part 2 may be too burdensome in these instances. For example, in the case of a hurricane, normal policies and procedures for obtaining consent according to current requirements may not be operational. At the same time, the inability of SUD patients to access needed care through their usual providers (or other providers) that have access to Part 2-protected records concerning their condition may constitute or lead to medical emergencies.

Conclusion

In order to address the nation's opioid crisis, SUD patients must be given the treatment they require, and practices must have the information they need to appropriately treat those suffering from SUD. The significant challenge facing the industry, however, is balancing the need for SUD information to be disclosed to appropriate treatment providers with the critical need to keep that information secure from inappropriate access. Patients who fear their sensitive information will be disclosed to individuals or entities without approval will avoid seeking treatment. Improving the flow of appropriately disclosed information, for example through the use of PDMPs, will go a long way toward addressing the opioid crisis. Should you have any questions regarding these comments, please contact Robert Tennant, Director, Health Information Technology Policy, at 202.293.3450 or rtennant@mgma.org.

Sincerely,

/s/

Anders Gilberg, MGA
Senior Vice President, Government Affairs