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October 25, 2019

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

RE: SAMHSA-4162-20; Confidentiality of Substance Use Disorder Patient Records

Dear Secretary Azar:

The Medicaid and CHIP Payment and Access Commission (MACPAC) appreciates the opportunity to comment on the U.S. Department of Health and Human Services proposed rule on Substance Use Disorder Confidentiality of Patient Records, 84 Fed. Reg. 44568 (August 26, 2019).

MACPAC is a non-partisan legislative branch agency that provides policy and data analysis and makes recommendations to Congress, the Secretary of the U.S. Department of Health and Human Services (HHS), and the states on a wide range of topics related to Medicaid and the State Children's Health Insurance Program (CHIP).

The Commission recognizes that the proposed changes to 42 CFR Part 2 (Part 2) represent modest improvements; however, they do not address important concerns about lack of clarity in Part 2 that may be impeding appropriate information sharing. Specifically, confusion among providers and payers about how to comply with Part 2 serves as a barrier to care coordination for individuals with a substance use disorder (SUD).

Prior MACPAC work and recommendations

The Commission's interest in Part 2 stems from concerns that mental health and SUD treatment for Medicaid beneficiaries is not well coordinated with physical health care. In part, the strict confidentiality requirements related to SUD patient medical records can create a barrier to coordinated care. We discussed this issue in our March 2016 report to Congress and again in our June 2017 report.

In 2018, MACPAC undertook additional work to better understand how Part 2



affects care delivery for Medicaid and CHIP beneficiaries who have SUDs and to explore options for promoting information sharing. As part of this effort, we convened an expert roundtable of federal and state Medicaid and behavioral health officials, health care providers, legal experts, researchers, Medicaid managed care organizations, and patient advocates. Through the roundtable, MACPAC sought input on several issues: (1) why Part 2 protections are needed; (2) how Part 2 affects Medicaid care delivery and exchange of SUD treatment information; and (3) any needed changes to Part 2 to support care integration, while protecting individuals from discrimination.

In our June 2018 report, MACPAC shared what we learned from the roundtable and our other analyses. Specifically, we highlighted that:

- Part 2 consent requirements are confusing to providers, payers, and patients in terms of the individuals and entities to whom information can be disclosed and how patients may specify what kind of information can be disclosed. There is also confusion regarding when general designations can be used to share Part 2 protected information.
- Confusion about Part 2 may arise because requirements under the Health Insurance Portability and Accountability Act (HIPAA, P.L. 104-191) that govern privacy of most other patient information are generally less stringent than Part 2, permitting providers and plans to share information for payment, treatment, and health care operations purposes without patient consent. While Part 2 rules promulgated in 2018 allow redisclosure without additional patient consent to contractors and subcontractors for payment and health care operations activities, they are not permitted for treatment purposes. Classifying care coordination and case management as patient safety activities rather than treatment would allow payers to redisclose this information to contractors and subcontractors (MACPAC 2018).
- There are other barriers to sharing SUD treatment information, including challenges related to transmission of Part 2 protected information within electronic health records (EHRs). Many community-based Part 2 treatment providers have not adopted EHRs. Even when providers are using EHRs, Part 2 protected information must be segmented from other information that is only subject to HIPAA. Moreover, there are currently no federal requirements that EHRs include functionality to comply with Part 2 and there is disagreement as to whether and to what degree widespread Part 2-compliant interoperability is technically feasible (MACPAC 2018).
- Information on pharmacotherapies used to treat SUDs is not present in prescription drug monitoring programs (PDMPs). This limits the effectiveness of PDMPs in helping providers avoid potentially fatal drug interactions and identify patients who may be at risk for prescription drug misuse, and identify providers with inappropriate prescribing patterns.

To address these concerns, MACPAC recommended in June 2018 that the Secretary issue clarifying guidance of key aspects of Part 2 regulations that Medicaid and CHIP stakeholders have identified as ambiguous and confusing, including:



- which providers are covered by Part 2, including whether providers prescribing buprenorphine or SUD specialists practicing in multispecialty settings are covered;
- the meaning of the phrase “holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment”;
- which information must be protected, including that related to non-SUD medical care delivered to patients in SUD treatment settings, medical care for illnesses associated with SUD, and medications used to treat SUD; and
- which entities or individuals within a Part 2 program can share SUD information with each other without patient consent and whether SUD information must be segregated in electronic health records accessible to other providers within the Part 2 program.

We also recommended that the Secretary direct a coordinated effort by relevant agencies to provide education and technical assistance on 42 CFR Part 2.

Comments on proposed rule

The proposed rule would make modest changes to Part 2 to facilitate better care coordination for individuals with an SUD, including allowing patients to disclose Part 2 information to a broader range of entities. MACPAC supports the proposed changes to allow opioid treatment programs to disclose dispensing and prescribing data to PDMPs, subject to patient consent. This is an important change that will improve care coordination for individuals with an SUD.

MACPAC appreciates the Administration’s proposal to amend Part 2 to allow patients to consent to disclosures of Part 2 information to organizations with which they do not have a treating provider relationship. Allowing individuals, including Medicaid beneficiaries, to disclose SUD treatment information to a wider range of entities without naming a specific person as the recipient for the disclosure will improve the sharing of Part 2 information. Importantly, it will give individuals the ability to disclose protected information for the purposes of determining eligibility for state or federal benefits.

While MACPAC appreciates these changes, the proposed rule does little to address the concerns documented in the Commission’s June 2018 report to Congress, including those related to payment, treatment, and health care operations, as well as EHRs. HHS continues to explicitly exclude care coordination and case management functions from its list of permissible activities because, as discussed in the preambles to the 2017 and 2018 rules, as well as the 2019 proposed rule, it considers those functions to include a treatment component (MACPAC 2018). The proposed rule also acknowledges that this approach differs from HIPAA, under which health care operations encompass such activities as case management and care coordination. Such differences between HIPAA and Part 2 create further confusion among providers.

The proposed rule does not establish any new standards or requirements for EHR technology as it relates to Part 2. While we commend the steps taken by the Substance Abuse and Mental Health Services



Administration and the Office of the National Coordinator for Health Information Technology to illustrate how Part 2 may apply to certain providers, patient information, and disclosures through electronic health information exchanges, sharing Part 2 protected information electronically remains challenging for the reasons outlined above.

It is the Commission's view that HHS could make additional clarifications to reduce confusion related to Part 2 and improve care coordination for individuals with SUDs, without creating undue risk for individuals seeking treatment. Additional clarification to Part 2 could be achieved without causing "serious consequences [to individuals seeking SUD services] including criminal arrest, prosecution, and incarceration; loss of employment, housing, or child custody; discrimination by medical professionals; and denial of life or disability insurance" (MACPAC 2018). Moreover, we continue to hold that education and technical assistance is needed to ensure that providers and plans are fully aware of how and when information can be shared and that beneficiaries understand under what circumstances information is protected and when and how they can provide consent to share that protected information with others.

We appreciate the opportunity to provide comments on this proposed regulation.

Sincerely,



Melanie Bella, MBA
Chair

cc: The Honorable Chuck Grassley, Chairman, Committee on Finance, U.S. Senate
The Honorable Ron Wyden, Ranking Member, Committee on Finance, U.S. Senate
The Honorable Frank Pallone Jr., Chairman, Committee on Energy and Commerce, U.S. House of Representatives
The Honorable Greg Walden, Ranking Member, Committee on Energy and Commerce, U.S. House of Representatives

References

Medicaid and CHIP Payment and Access Commission (MAPAC). 2018. Chapter 2: Substance use disorder confidentiality regulations and care integration in Medicaid and CHIP. In *Report to Congress on Medicaid and CHIP*. June 2018. Washington, DC: MACPAC. <https://www.macpac.gov/wp-content/uploads/2018/06/Substance-Use-Disorder-Confidentiality-Regulations-and-Care-Integration-in-Medicaid-and-CHIP.pdf>.