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January 31, 2023

The Honorable Xavier Becerra  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201

**Re: HHS–OCR–0945–AA1: Confidentiality of Substance Use Disorder (SUD) Patient Records**

Dear Secretary Becerra:

The Medicaid and CHIP Payment and Access Commission (MACPAC) appreciates the opportunity to comment on the notice of proposed rulemaking (NPRM) on Confidentiality of Substance Use Disorder (SUD) Patient Records published on December 2, 2022 (87 Fed. Reg., 74216), and promulgated by the Office for Civil Rights (OCR) and Substance Abuse and Mental Health Services Administration (SAMHSA). 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 proposed rule implements section 3221 of the Coronavirus Aid, Relief, and Economic Security Act (CARES, P.L. 116-136), which aligns certain 42 CFR Part 2 (Part 2) requirements with Health Insurance Portability and Accountability Act (HIPAA, P.L. 104-191) rules for protected health information (PHI). These are important changes intended to improve care coordination for individuals with SUD and ease the compliance burden on Part 2 providers while enhancing their rights and protections as patients.

The Commission's interest in Part 2 stems from concerns that Medicaid beneficiaries lack access to SUD treatment, and that the SUD services they receive are not well coordinated with their physical health care. The strict confidentiality requirements related to SUD records can create a barrier to coordinated care, which affects patient safety, such as when a provider unknowingly prescribes an opioid pain reliever to an individual with an opioid use disorder (MACPAC 2018). At the same time, the Commission recognizes the importance of adequate safeguards to ensure that individuals are not deterred from seeking SUD treatment or subject to bias in SUD treatment and other negative consequences, such as criminal prosecution or employment discrimination.

The Commission is broadly supportive of HHS's efforts to improve the ability of patients and providers to share SUD information, while strengthening patient rights and protections. These changes are critical steps toward improving the availability and quality of SUD treatment. However, the Commission is concerned about the stricter consent requirements proposed for intermediaries as well as HHS's decision



to implement new antidiscrimination protections in separate rulemaking. Due to the scope of changes required to align Part 2 and HIPAA, MACPAC believes that clear and timely implementation guidance is necessary. This includes encouraging HHS to develop a voluntary certification for information technology (IT) practiced in integrated care and behavioral health settings, and providing education and technical assistance to support Part 2 compliance and ensure that individuals understand their patient rights and protections afforded to them under the new rules.

## Prior MACPAC Work and Recommendations

MACPAC's prior work found that there was significant confusion among stakeholders regarding the scope and applicability of Part 2, which can lead to its inconsistent application and may hamper care coordination and care transitions. Confusion about Part 2 may arise, in part, because HIPAA requirements that govern privacy of most other patient information are generally less stringent than Part 2 rules, permitting providers and plans to share information for treatment, payment, and health care operations (TPO) purposes without patient consent.

To address these concerns, in June 2018, MACPAC recommended that the Secretary issue subregulatory guidance to clarify key aspects of Part 2 regulations that Medicaid and CHIP stakeholders identified as ambiguous and confusing. The Commission also recommended that the Secretary direct a coordinated effort by relevant agencies to provide education and technical assistance on Part 2.

The Commission has examined other barriers to coordinated care for beneficiaries with SUD, including challenges related to segmenting Part 2 records from other information within electronic health records (EHRs). This requirement contributes to low rates of EHR adoption among behavioral health providers, which in turn limits clinical integration of care for beneficiaries with behavioral health conditions. While data tagging and segmentation capabilities have been developed, they have not been widely incorporated into certified EHR technology used by many Medicaid-enrolled providers. To encourage the development and use of EHR products that permit segmentation of protected SUD information, in June 2022, the Commission recommended that the Office of the National Coordinator for Health Information Technology (ONC) and SAMHSA develop a voluntary certification for IT used in integrated care and behavioral health settings that supports segmentation such that providers can comply with state and federal privacy security laws, including Part 2 (MACPAC 2022, 2018).

## Comments on Proposed Rule

MACPAC is encouraged by the potential for this proposed rule to address low rates of treatment among Medicaid beneficiaries and others with SUD. In 2021, only 6.3 percent of people with SUD reported receiving any form of SUD treatment (SAMHSA 2022). By aligning elements of Part 2 and HIPAA, the proposed rule will reduce the administrative burdens that may deter many providers from offering SUD treatment. These changes to Part 2, along with a provision in the Consolidated Appropriations Act, 2023 (P.L. 117-328) that makes it easier to prescribe buprenorphine for the treatment of opioid use disorder, could help improve beneficiary access to SUD treatment. MACPAC supports proposed changes that would allow individuals to consent to the disclosure of their SUD treatment information to a wide range of entities without naming a specific person or organization as the recipient. Doing so will facilitate the sharing of Part 2 information to support care coordination and care quality (MACPAC 2019). MACPAC holds that if an individual has provided consent to share their Part 2 records, that information should be accessible to other organizations, including to organizations with whom the individual with an SUD diagnosis does not have a treating provider relationship.



However, the Commission is concerned that the proposed rule requires specific consent for disclosures to intermediaries, such health information exchanges (HIEs). In these instances, patient consent forms must name the specific intermediary, whereas forms authorizing disclosure to other organizations may describe a category of individuals permitted to receive that information, rather than the names of potential recipients. Different and more stringent consent requirements for certain intermediaries could result in confusion for providers, intermediaries, and individuals with an SUD diagnosis, and impede the sharing of Part 2 information to entities that support care coordination.

MACPAC believes strongly in privacy protections that provide safeguards for individuals receiving SUD treatment. Additional protections against the use of SUD records in criminal, civil, administrative, and legislative proceedings included in the proposed rule, as well as stronger federal enforcement of Part 2 rules, are important to ensuring that individuals can seek care for their SUD without fear of negative consequences. However, the Commission is concerned that the exclusion of anti-discrimination provisions established by the CARES Act may discourage care-seeking for SUD treatment. MACPAC encourages HHS to engage in rulemaking implementing the anti-discrimination provisions, and take steps to ensure that greater data sharing does not exacerbate racial and ethnic inequities in SUD access and outcomes.

While the proposed rule would increase alignment between Part 2 and HIPAA, the continued need for segmentation of Part 2 records in certain instances (e.g., when an individual requests restriction on the disclosure of their Part 2 information) reinforces the need of EHRs to maintain Part 2 information separately. The Commission has found that behavioral health providers encounter challenges purchasing an EHR that can adequately segment Part 2 information, which contributes to low rates of EHR adoption; in 2017, only 29 percent of these providers had an EHR (MACPAC 2021a). The lack of EHR use among many behavioral health providers limits their participation in HIEs and impedes clinical integration of care for beneficiaries with behavioral health conditions (MACPAC 2022). To encourage the development and use of EHR products that permit segmentation of protected SUD information, ONC and SAMHSA should develop a voluntary certification for behavioral health IT that supports the continued need for segmentation of Part 2 information. Furthermore, providing subregulatory guidance on which EHRs are suitable for behavioral health and integrated care settings would help SUD providers purchase an EHR that meets their needs (MACPAC 2022).

Greater alignment between Part 2 and HIPAA is intended to provide consistency between and address points of confusion about the privacy rules. However, given the unprecedented scope of changes to Part 2, there will be a continued need for timely subregulatory guidance, as well as education and technical assistance to support compliance with Part 2 requirements. Stakeholders will be important partners for identifying key areas of confusion in need of clarification. A coordinated effort by Centers for Medicare & Medicaid Services, SAMHSA, OCR, and ONC regarding education and technical assistance will be necessary to ensure that providers and plans are fully aware of when SUD information can be shared and that beneficiaries understand when their data is protected and when it is not (MACPAC 2022a, 2018). For example, providers and plans may find it helpful to have a template for the Notice of Privacy Practices (NPP) pursuant to Part 2 regulations. Such a template should be written in plain language and accessible in multiple languages. An NPP template would facilitate provider compliance with changes to Part 2 regulations, while also helping to ensure that individuals understand their rights and protections as patients.

The changes proposed in this rule are an important step toward improved access to SUD treatment and better care for Medicaid beneficiaries and other individuals with SUD. However, some stakeholders believe that Part 2 and HIPAA should be further aligned (MACPAC 2018). Whether more fundamental changes are needed to enhance the availability and quality of SUD treatment is a question that the Commission plans to explore in the future.



Thank you for the opportunity to comment on this proposed rule. MACPAC welcomes questions from HHS as it implements this rule.

Sincerely,



Melanie Bella, MBA  
Chair

cc: The Honorable Ron Wyden, Chair, Senate Finance Committee  
The Honorable Mike Crapo, Ranking Member, Senate Finance Committee  
The Honorable Cathy McMorris Rodgers, Chair, House Energy and Commerce Committee  
The Honorable Frank Pallone Jr., Ranking Member, House Energy and Commerce Committee

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