MACPAC

Proposed Rule on Substance Use Disorder Confidentiality of Patient Records

Medicaid and CHIP Payment and Access Commission

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Overview

- Background
- Prior MACPAC work
- Current regulation and proposed changes
- Potential areas for comment
  - Comments due October 25, 2019

Background: 42 CFR Part 2

- Governs disclosure of substance use disorder (SUD) treatment and prevention records
- Regulations first promulgated in 1975, but many requirements defined in statue
- Intended to encourage individuals who may fear negative consequences to seek treatment

Background: 42 CFR Part 2 (cont.)

Statute include provisions that:

- Require Part 2 providers to obtain written patient consent to disclose SUD treatment records
- Prohibit law enforcement access to SUD treatment information, absent court order
- Exempt from the prior written consent requirement disclosures made in certain circumstances (e.g. medical emergencies, scientific research, program evaluation)
- Charge the Secretary of HHS with issuing regulations to carry out the law

Prior MACPAC Work

In June 2018 report to Congress, MACPAC made two recommendations regarding Part 2 regulations:

- Commission recommended that HHS clarify key Part 2 provisions to identify:
  - which providers are subject to Part 2, including providing additional definitions for certain terms
  - which information must be protected
  - how information can be shared in a Part-2 compliant manner
  - when patients can use general designations
- Commission also recommended HHS should direct a coordinated effort to provide education and technical assistance on Part 2

Current Regulation and Proposed Changes: Applicability of Part 2

Current regulation

- Part 2 applies to federally-assisted programs that "holds itself out" as providing SUD care

Proposed change

- NPRM clarifies that patient records created by non-Part 2 providers, based on their own patient encounters, are not subject to Part 2, unless SUD records previously received from a Part 2 provider are incorporated into the non-Part 2 provider's records
- Segmentation would ensure that new records created by non-Part 2 providers would not become subject to Part 2

MACPAC recommendations

- MACPAC focused on clarifying which providers were covered by Part 2, as opposed to making clarifications for non-Part 2 providers

Current Regulation and Proposed Changes: When Patient Consent is Required

Current regulation

- Limited circumstances when information can be disclosed or redisclosed without patient consent (e.g., medical emergencies, for research, audit and evaluation)

Proposed change

- Amends definition of medical emergency
- Broadens disclosure exception for research purposes
- Clarifies when information can be disclosed for audit and evaluation purposes

MACPAC recommendations

- MACPAC did not make recommendations related to these provisions in the June 2018 report

Current Regulation and Proposed Changes: Consent Requirements

Current regulation

In the consent form, patients must specify who may receive the information by identifying one of the following:

- the name of an individual;
- the name of an entity, as long as it has a treating provider relationship with the patient;
- the name of a third-party payer; or
- the name of an intermediary entity without a treating provider relationship that shares information with participants in that entity

Proposed change

- NPRM would allow patients to consent to the disclosure of their SUD information to a wider range of entities without naming a specific person as the recipient for the disclosure

MACPAC recommendations

- MACPAC noted SAMHSA needed to further define when a patient can use a general designation to identify recipients to whom information is to be disclosed, and when a treating provider relationship exists

Current Regulation and Proposed Changes: Redisclosure of Information

Current regulation

Redisclosure only permitted without patient consent in limited circumstances:

- carrying out Medicare, Medicaid, and CHIP audits and evaluations (42 CFR 2.53); and
- an entity (e.g., Medicaid MCO) that, pursuant to a patient's consent, receives protected information for purposes of payment or health care operational activities, may redisclose that information to others only if the redisclosure is necessary for carrying out the activities for which the initial consent was granted (42 CFR 2.33)

Proposed change

- This is not a material change. Rather, NPRM moves information from the preamble into the regulatory text

MACPAC recommendations

- MACPAC did not make a recommendation related to this provision in its June 2018 report

Current Regulation and Proposed Changes: Other Provisions

Undercover agents

- Part 2 has a process for authorizing undercover agents to ensure the safety of patients in these Part 2 programs.
- NPRM increases the length of time that a court-ordered undercover agent or informant may be placed within a Part 2 program

Disclosure to prescription drug monitoring programs and central registries

- NPRM proposes to allow opioid treatment programs (OTPs) to disclose dispensing and prescribing data to PDMPs subject to patient consent
- Proposed change reverses 2011 SAMHSA guidance
- NPRM also permits non-OTP providers to query certain registries to determine whether their patients are already receiving treatment

Disposition of records

- NPRM proposes that if a patient sends an incidental message, such as a text or email, to the personal device (e.g., cell phone) of an employee of a Part 2 program, the employee will be able to fulfill Part 2 requirements by deleting that message

Potential Areas for Comment

- Areas where the NPRM seeks to improve care coordination
- Reinforce recommendations made in the June 2018 report to Congress that remain unaddressed
- Comments are due October 25, 2019, prior to next Commission meeting

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