U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE FOR CIVIL RIGHTS

Part 2 Confidentiality Requirements for Substance Use Disorder (SUD) Patient Records and Exclusion from the Medicaid Community Engagement Requirement for Certain Individuals with SUD

The Confidentiality of Substance Use Disorder (SUD) Patient Records regulation, 42 CFR part 2 ("**Part 2**"), protects certain records about patients related to services for SUD. Part 2 describes when and how certain SUD patient records ("**Part 2 records**"[1]) may be used and disclosed.[2]

Part 2 requirements generally apply to any federally assisted program that provides SUD diagnosis, treatment, or referral for treatment[3] ("**Part 2 programs**"[4]). Some Part 2 requirements also apply to people and organizations who receive Part 2 records from a Part 2 program, such as health plans that pay for SUD treatment and government health benefits programs such as Medicaid.

Federal law generally requires certain adults (ages 19–64) who are Medicaid applicants or beneficiaries to engage in work, community service, or certain other activities for 80 hours per month, or be enrolled at least half-time in education, to be eligible for Medicaid.[5] However, the[6]statute and its implementing regulation exclude certain categories of individuals ("specified excluded individuals") from the community engagement requirement, such as individuals who are medically frail or otherwise have special medical needs (including certain individuals with SUD)[7] and individuals who are participating in

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[1] *See* 42 CFR 2.11 (definition of "Records").
[2] *See* 42 CFR 2.2.
[3] *See* 42 CFR 2.12. The Part 2 statute (42 U.S.C. 290dd-2) protects "[r]ecords of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance use disorder education, prevention, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States."
[4] *See* 42 CFR 2.11 (definition of "Part 2 program").
[5] *See* 42 U.S.C. 1396a(xx). The Centers for Medicare & Medicaid Services (CMS) published an interim final rule with a comment period that interprets and implements the community engagement requirement in Medicaid under section 1902(xx) of the Social Security Act (42 U.S.C. 1396a(xx)). States are required to implement the new requirement no later than January 1, 2027. *See* Medicaid Program; Community Engagement Requirement for Certain Individuals, Interim final rule with comment period, 91 FR 33348 (June 3, 2026).
[6] *See* 42 U.S.C.1396a(xx)(9)(A)(ii); 42 CFR 435.554.
[7] *See* 42 U.S.C. 1396a(xx)(9)(A)(ii)(V); 42 CFR 435.554(c)(5). CMS established the definition of an individual who is medically frail or otherwise has special medical needs for purposes of the community engagement requirement at 42 CFR 435.554(c)(5)(i), and excluded individuals who are in stable recovery (which means individuals who are in recovery for 5 or more years) from the SUD category of that definition at 42 CFR 435.554(c)(5)(i)(B). In addition, the definition at 42 CFR 435.554(c)(5)(i) requires that an individual's physical, mental, or other behavioral health condition significantly impairs the individual's ability to comply with the community engagement requirement for the individual to meet the definition of an individual who is medically frail or otherwise has special medical needs.

certain SUD treatment programs.[8] The statute and its implementing regulation also require a state to use reliable information it has available to verify the applicant's or beneficiary's compliance with or exclusion from the community engagement requirement (such as health care encounter data for individuals and data on payments for Medicaid services provided to such individuals from the preceding 12 months) without requiring, where possible, the individual to submit additional information.[9]

In the preamble to the interim final rule on the community engagement requirement, the Centers for Medicare & Medicaid Services recognized that processes for the identification and verification of individuals who may be specified excluded individuals intersect with Part 2, and stated its intention to work with OCR to provide technical assistance to states on this intersection.[10] Accordingly, this guidance addresses how Part 2 applies when a state Medicaid agency has Part 2 records that could help the agency verify that an applicant or beneficiary is a specified excluded individual.

When does 42 CFR part 2 ("Part 2") permit a state Medicaid agency to use an applicant's or beneficiary's substance use disorder (SUD) patient records protected under Part 2 to verify an exclusion from the community engagement requirement?

A state Medicaid agency is permitted to use Part 2 records to verify that a Medicaid applicant or beneficiary meets the definition of a specified excluded individual,[11] and thus is excluded from the community engagement requirement as a condition of Medicaid eligibility, in the following circumstances:[12]

[8] *See* 42 U.S.C. 1396a(xx)(9)(A)(ii)(VII); 42 CFR 435.554(c)(8).
[9] *See* 42 U.S.C. 1396a(xx)(5); 42 CFR 435.557.
[10] *See* 91 FR 33348, 33407.
[11] *See* 42 U.S.C. 1396a(xx)(9)(A)(ii); 42 CFR 435.554.
[12] Any Part 2 records used or disclosed as described in this guidance remain subject to the prohibition on the use and disclosure of those records to initiate or substantiate criminal charges against a patient or to conduct any criminal investigation of a patient, or to use in any civil, criminal, administrative, or legislative proceedings against a patient. *See* 42 CFR 2.12(d)(1). This also applies to Part 2 records obtained by the patient and disclosed directly to a recipient. *See* 42 CFR 2.23(b). A separate patient consent is required for the use or disclosure of Part 2 records in a civil, criminal, administrative, or legislative investigation or proceeding against the patient. *See* 42 CFR 2.31(d).

- *The state Medicaid agency uses Part 2 records to verify an exclusion, consistent with a written patient consent previously obtained by a Part 2 program for all future uses and disclosures for treatment,[13] payment,[14] and health care operations[15] purposes.*
    - *Example:* A Part 2 program obtains a patient's written consent for all future uses and disclosures of his or her Part 2 records for treatment, payment, and health care operations purposes ("TPO consent"). The TPO consent allows the Part 2 program to disclose the patient's Part 2 records to a state Medicaid agency for treatment, payment, and health care operations purposes, such as to file a claim for health care.[16] The Part 2 program provides a copy of the consent (or a clear explanation of the scope of the consent) to accompany the Part 2 records, as required by Part 2.[17] Based on this consent, the state Medicaid agency that receives the Part 2 records can later use the records for treatment, payment, and health care operations[18]—including to verify the applicant's or beneficiary's exclusion from the community engagement requirement—without obtaining an additional patient consent.[19]
- *The state Medicaid agency obtains written patient consent to use a patient's Part 2 records to verify an exclusion.[20]*
    - *Example 1:* A state Medicaid agency obtains an applicant's or a beneficiary's written consent for the state Medicaid agency to use their Part 2 records already held by the agency for the specific purpose of determining whether an exclusion from the community engagement requirement applies.[21]
    - *Example 2:* A state Medicaid agency obtains an applicant's or a beneficiary's written consent for the use of their Part 2 records already held by the agency

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[13] *See* 42 CFR 2.11 (definition of "Treatment") (referring to the definition in the HIPAA Rules at 45 CFR 164.501).
[14] *See* 42 CFR 2.11 (definition of "Payment") (referring to the definition in the HIPAA Rules at 45 CFR 164.501). Payment includes determining eligibility or coverage under a health plan.
[15] *See* 42 CFR 2.11 (definition of "Health care operations") (referring to the definition in the HIPAA Rules at 45 CFR 164.501). Health care operations includes enrollment and disenrollment in a health plan.
[16] *See* 42 CFR 2.33(a)(2).
[17] *See* 42 CFR 2.32(b). Each disclosure with a patient's written consent also must be accompanied by a statement explaining that Part 2 prohibits unauthorized use or disclosure of the records. Part 2 provides for two statements, either of which will fulfill this requirement. *See* 42 CFR 2.32(a).
[18] *See* 42 CFR 2.33(a)(2).
[19] Determining whether a Medicaid applicant or beneficiary is excluded from the community engagement requirement may involve both health care operations and payment activities.
[20] In the examples below, the state Medicaid agency may have received the Part 2 records based on a consent other than a TPO consent (*e.g.*, a consent for a Part 2 program to disclose Part 2 records to the state Medicaid agency for payment purposes).
[21] *See* 42 U.S.C. 290dd-2(b)(1)(A).

for all future uses and disclosures for treatment, payment, and health care operations, which would include determining whether an exclusion from the community engagement requirement applies. [22]

A written consent that a state Medicaid agency obtains must include the required elements specified in 42 CFR 2.31(a), including the patient's right to revoke consent and an expiration date or event.

[22] *See* 42 U.S.C. 290dd-2(b)(1)(B); 42 CFR 2.33(a)(2).