

Audit and Evaluation (b) Guide

A Part 2 program may disclose patient records to entities engaged in certain audit or evaluation activities on behalf of CMS, Medicaid, an MCO, or a third-party payer.

A. Is your entity receiving Part 2 protected information?

1. [THIS ASSUMPTION IS MADE FOR PURPOSES OF THE PRESENTATIONS]

B. Is your entity receiving the Part 2 protected information from the Part 2 program or a lawful holder of the Part 2 information?

1. Definitions
 - Receiving: “Receiving” information includes information that is copied, removed, downloaded, or forwarded.¹
 - Lawful Holder: A “lawful holder” of patient identifying information is an individual or entity who has received such information as the result of a Part 2-compliant patient consent (with a prohibition on re-disclosure notice) or as permitted under the Part 2 statute, regulations, and guidance, and therefore is bound by 42 CFR Part 2.²

C. Is your entity performing the function of an audit or evaluation?

1. Examples of audits or evaluations include broad regulating activities including the need to review records to appropriately evaluate compliance with applicable policies, rules, and laws, including waivers and state plans.

D. Is your entity performing the audit or evaluation on behalf of:

1. **DHHS/Medicaid** (as a state authority that provides financial assistance to or regulates a Part 2 program or lawful holder)?³
2. A **third-party payer** covering patients in the Part 2 program?⁴
3. A **quality improvement organization**, or its agent, performing a:⁵
 - Utilization review?
 - Quality control review?

E. Does your entity have a written agreement?

1. If your entity is receiving Part 2 protected information because you are performing an audit or evaluation as outlined above, or your entity is ordering the audit or evaluation, then you must agree in writing to (all 4 are required):
 - Maintain and destroy the patient identifying information consistent with the formal policies and procedures in place to protect the Part 2 information⁶; and
 - Retain records in compliance with federal, state, and local laws⁷; and
 - Use the patient identifying information solely for the purpose of carrying out an audit or evaluation⁸; and

¹ 42 CFR Part 2, § 2.53(b).

² 42 CFR Part 2 Final Rule, January 18, 2017, p. 6068.

³ 42 CFR Part 2, § 2.53(b)(2)(i)

⁴ 42 CFR Part 2, § 2.53(b)(2)(ii).

⁵ 42 CFR Part 2, § 2.53(b)(2)(ii).

⁶ 42 CFR Part 2, § 2.53(b)(1)(i), § 2.16.

⁷ 42 CFR Part 2, § 2.53(b)(1)(ii).

⁸ 42 CFR Part 2, § 2.53(b)(1)(iii).

- Not disclose the patient identifying information except back to the Part 2 program or lawful holder from which it came⁹.

F. Can your entity (if it's performing the audit or evaluation or ordering the audit or evaluation) re-disclose the Part 2 protected information?

1. If the audit or evaluation is being performed on your behalf, the agent performing the audit or evaluation can re-disclose for purposes of the audit or evaluation.¹⁰
2. If you are ordering the audit or evaluation your entity can only re-disclose to an agent for that purpose.¹¹

⁹ 42 CFR Part 2, § 2.53(b)(1)(iii).

¹⁰ 42 CFR Part 2, § 2.53(d); 42 CFR Part 2 Final Rule, January 3, 2018, p. 246.

¹¹ 42 CFR Part 2, § 2.53(d).