Audit and Evaluation (c) Guide

Patient identifying information may be disclosed to any individual or entity who is conducting a Medicare, Medicaid, or CHIP audit or evaluation. This includes a "CMS-regulated" entity.

A. Is a Part 2 provider exchanging Part 2 protected information with an IDN?

B. Is the IDN regulated by CMS?

1. Examples of circumstances that make an entity CMS-regulated[1]:
    - Organization is required to meet CMS audit and evaluation requirements
    - Direct supervision by CMS
    - CMS established regulations governing conduct or qualification
    - *CMS approval of state plans or waivers (for Medicaid and CHIP)*

C. Does the IDN have in place…? (all are required):

1. Administrative and/or clinical systems; and
2. A leadership and management structure (including a governing body and CEO who oversees management and CMS agreement compliance); and
3. A signed participation agreement with CMS (or similar document), stating (all are required):
    - It is subject to periodic evaluations by CMS; and
    - It has designated an Executive with authority to bind the organization; and
    - The audit or evaluation will occur in a confidential and controlled setting approved by the Executive, and follow policies and procedures that do not allow for direct or indirect identification of the patient.

D. Does the IDN have a written agreement?

1. If the IDN is regulated by CMS under the CMS approval of state plans or waivers example, then the IDN 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 information[2]; and
    - Retain records in compliance with federal, state, and local laws[3]; and
    - Use the patient identifying information solely for the purpose of carrying out an audit or evaluation[4]; and
    - Not disclose the patient identifying information except back to the Part 2 program or lawful holder from which it came[5].

E. Can the IDN re-disclose the Part 2 protected information?

1. Yes, but only for the purposes of the audit or evaluation.[6]

[1] 42 CFR Part 2 Final Rule, January 18, 2017, p. 6103.
[2] 42 CFR Part 2, § 2.53(c)(1)(i), § 2.16.
[3] 42 CFR Part 2, § 2.53(c)(1)(ii).
[4] 42 CFR Part 2, § 2.53(c)(1)(iii).
[5] 42 CFR Part 2, § 2.53(c)(1)(iii).
[6] 42 CFR 2.53(c)(5).