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:\n      • 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):\n   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\n; and
      • Retain records in compliance with federal, state, and local laws\n; and
      • Use the patient identifying information solely for the purpose of carrying out an audit or evaluation\n; and
      • Not disclose the patient identifying information except back to the Part 2 program or lawful holder from which it came\n.

E. Can the IDN re-disclose the Part 2 protected information?
   1. Yes, but only for the purposes of the audit or evaluation\n.

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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).