
42 C.F.R. § 2.53

Management audits, financial audits, and program evaluation.

(a) *Records not copied or removed.* If patient records are not downloaded, copied or removed from the premises of a part 2 program or other lawful holder, or forwarded electronically to another electronic system or device, patient identifying information, as defined in § 2.11, may be disclosed in the course of a review of records on the premises of a part 2 program or other lawful holder to any person who agrees in writing to comply with the limitations on use and redisclosure in paragraph (f) of this section and who:

(1) Performs the audit or evaluation on behalf of:

(i) Any federal, state, or local governmental agency that provides financial assistance to a part 2 program or other lawful holder, or is authorized by law to regulate the activities of the part 2 program or other lawful holder;

(ii) Any person which provides financial assistance to the part 2 program or other lawful holder, which is a third-party payer or health plan covering patients in the part 2 program, or which is a quality improvement organization (QIO) performing a QIO review, or the contractors, subcontractors, or legal representatives of such person or quality improvement organization; or

(iii) An entity with direct administrative control over the part 2 program or lawful holder.

(2) Is determined by the part 2 program or other lawful holder to be qualified to conduct an audit or evaluation of the part 2 program or other lawful holder.

(b) *Copying, removing, downloading, or forwarding patient records.* Records containing patient identifying information, as defined in § 2.11, may be copied or removed from the premises of a part 2 program or other lawful holder or downloaded or forwarded to another electronic system or device from the part 2 program's or other lawful holder's electronic records by any person who:

(1) Agrees in writing to:

(i) Maintain and destroy the patient identifying information in a manner consistent with the policies and procedures established under § 2.16;

(ii) Retain records in compliance with applicable federal, state, and local record retention laws; and

(iii) Comply with the limitations on use and disclosure in paragraph (f) of this section; and

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