

§ 401.722

and its contractors must immediately upon receipt of notification of the termination commence returning or destroying any and all CMS data (and any derivative files). In no instance can this process exceed 30 days.

(2) If a qualified entity voluntarily terminates participation under this subpart, it and its contractors must return to CMS, or destroy, any and all CMS data in its possession within 30 days of notifying CMS of its intent to end its participation.

[76 FR 76567, Dec. 7, 2011, as amended at 81 FR 44482, July 7, 2016]

§ 401.722 Qualified clinical data registries.

(a) A qualified clinical data registry that agrees to meet all the requirements in this subpart, with the exception of § 401.707(d), may request access to Medicare data as a quasi qualified entity in accordance with such qualified entity program requirements.

(b) Notwithstanding § 401.703(q) (generally defining combined data), for purposes of qualified clinical data registries acting as quasi qualified entities under the qualified entity program requirements, combined data means, at a minimum, a set of CMS claims data provided under this subpart combined with clinical data or a subset of clinical data.

[81 FR 44482, July 7, 2016]

PART 402—CIVIL MONEY PENALTIES, ASSESSMENTS, AND EXCLUSIONS

Subpart A—General Provisions

Sec.

- 402.1 Basis and scope.
- 402.3 Definitions.
- 402.5 Right to a hearing before the final determination.
- 402.7 Notice of proposed determination.
- 402.9 Failure to request a hearing.
- 402.11 Notice to other agencies and other entities.
- 402.13 Penalty, assessment, and exclusion not exclusive.
- 402.15 Collateral estoppel.
- 402.17 Settlement.
- 402.19 Hearings and appeals.
- 402.21 Judicial review.

42 CFR Ch. IV (10–1–23 Edition)

Subpart B—Civil Money Penalties and Assessments

- 402.105 Amount of penalty.
- 402.107 Amount of assessment.
- 402.109 Statistical sampling.
- 402.111 Factors considered determinations regarding the amount of penalties and assessments.
- 402.113 When a penalty and assessment are collectible.
- 402.115 Collection of penalty or assessment.

Subpart C—Exclusions

- 402.200 Basis and purpose.
- 402.205 Length of exclusion.
- 402.208 Factors considered in determining whether to exclude, and the length of exclusion.
- 402.209 Scope and effect of exclusion.
- 402.210 Notices.
- 402.212 Response to notice of proposed determination to exclude.
- 402.214 Appeal of exclusion.
- 402.300 Request for reinstatement.
- 402.302 Basis for reinstatement.
- 402.304 Approval of request for reinstatement.
- 402.306 Denial of request for reinstatement.
- 402.308 Waivers of exclusions.

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 63 FR 68690, Dec. 14, 1998, unless otherwise noted.

Subpart A—General Provisions

§ 402.1 Basis and scope.

(a) *Basis.* This part is based on the sections of the Act that are specified in paragraph (c) of this section.

(b) *Scope.* This part—

(1) Provides for the imposition of civil money penalties, assessments, and exclusions against persons that violate the provisions of the Act specified in paragraph (c), (d), or (e) of this section; and

(2) Sets forth the appeal rights of persons subject to penalties, assessments, or exclusion and the procedures for reinstatement following exclusion.

(c) *Civil money penalties.* CMS or OIG may impose civil money penalties against any person or other entity specified in paragraphs (c)(1) through (c)(34) of this section under the identified section of the Act. (The authorities that also permit imposition of an assessment or exclusion are noted in the applicable paragraphs.)