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(3) Whether assets have been concealed or improperly transferred by the debtor.

(b) *Basis for termination of collection action.* Bases on which CMS may terminate collection action on a claim include the following—

(1) *Inability to collect a substantial amount of the claim.* CMS may terminate collection action if it determines that it is unable to collect, or to enforce collection, of a significant amount of the claim. In making this determination, CMS will consider factors such as—

- (i) Judicial remedies available;
- (ii) The debtor's future financial prospects; and
- (iii) Exemptions available to the debtor under State or Federal law.

(2) *Inability to locate debtor.* In cases involving missing debtors, CMS may terminate collection action if—

- (i) There is no security remaining to be liquidated;
- (ii) The applicable statute of limitations has run; or
- (iii) The prospects of collecting by offset, whether or not an applicable statute of limitations has run, are considered by CMS to be too remote to justify retention of the claim.

(3) *Cost of collection exceeds recovery.* CMS may terminate collection action if it determines that the cost of further collection action will exceed the amount recoverable.

(4) *Legal insufficiency.* CMS may terminate collection action if it determines that the claim is legally without merit.

(5) *Evidence unavailable.* CMS may terminate collection action if—

- (i) Efforts to obtain voluntary payment are unsuccessful; and
- (ii) Evidence or witnesses necessary to prove the claim are unavailable.

§ 401.623 Joint and several liability.

(a) *Collection action.* CMS will liquidate claims as quickly as possible. In cases of joint and several liability among two or more debtors, CMS will not allocate the burden of claims payment among the debtors. CMS will proceed with collection action against one debtor even if other liable debtors have not paid their proportionate shares.

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(b) *Compromise.* Compromise with one debtor does not release a claim against remaining debtors. Furthermore, CMS will not consider the amount of a compromise with one debtor to be a binding precedent concerning the amounts due from other debtors who are jointly and severally liable on the claim.

§ 401.625 Effect of CMS claims collection decisions on appeals.

Any action taken under this subpart regarding the compromise of a claim, or suspension or termination of collection action on a claim, is not an initial determination for purposes of CMS appeal procedures.

Subpart G—Availability of Medicare Data for Performance Measurement

SOURCE: 76 FR 76567, Dec. 7, 2011, unless otherwise noted.

§ 401.701 Purpose and scope.

The regulations in this subpart implement section 1874(e) of the Social Security Act as it applies to Medicare data made available to qualified entities for the evaluation of the performance of providers and suppliers.

§ 401.703 Definitions.

For purposes of this subpart:

(a) *Qualified entity* means either a single public or private entity, or a lead entity and its contractors, that meets the following requirements:

- (1) Is qualified, as determined by the Secretary, to use claims data to evaluate the performance of providers and suppliers on measures of quality, efficiency, effectiveness, and resource use.
- (2) Agrees to meet the requirements described in this subpart at §§ 401.705 through 401.721.

(b) *Provider of services (referred to as a provider)* has the same meaning as the term “provider” in § 400.202 of this chapter.

(c) *Supplier* has the same meaning as the term “supplier” at § 400.202 of this chapter.

(d) *Claim* means an itemized billing statement from a provider or supplier that, except in the context of Part D prescription drug event data, requests

payment for a list of services and supplies that were furnished to a Medicare beneficiary in the Medicare fee-for-service context, or to a participant in other insurance or entitlement program contexts. In the Medicare program, claims files are available for each institutional (inpatient, outpatient, skilled nursing facility, hospice, or home health agency) and non-institutional (physician and durable medical equipment providers and suppliers) claim type as well as Medicare Part D Prescription Drug Event (PDE) data.

(e) *Standardized data extract* is a subset of Medicare claims data that the Secretary would make available to qualified entities under this subpart.

(f) *Beneficiary identifiable data* is any data that contains the beneficiary's name, Medicare Health Insurance Claim Number (HICN), or any other direct identifying factors, including, but not limited to postal address or telephone number.

(g) *Encrypted data* is any data that does not contain the beneficiary's name or any other direct identifying factors, but does include a unique CMS-assigned beneficiary identifier that allows for the linking of claims without divulging any direct identifier of the beneficiary.

(h) *Claims data from other sources* means provider- or supplier-identifiable claims data that an applicant or qualified entity has full data usage right to due to its own operations or disclosures from providers, suppliers, private payers, multi-payer databases, or other sources.

(i) *Clinical data* is registry data, chart-abstracted data, laboratory results, electronic health record information, or other information relating to the care or services furnished to patients that is not included in administrative claims data, but is available in electronic form.

(j) *Authorized user* is a third party and its contractors (including, where applicable, business associates as that term is defined at 45 CFR 160.103) that need analyses or data covered by this section to carry out work on behalf of that third party (meaning not the qualified entity or the qualified entity's contractors) to whom/which the

qualified entity provides or sells data as permitted under this subpart. Authorized user third parties are limited to the following entities:

- (1) A provider.
- (2) A supplier.
- (3) A medical society.
- (4) A hospital association.
- (5) An employer.
- (6) A health insurance issuer.
- (7) A healthcare provider and/or supplier association.
- (8) A state entity.
- (9) A federal agency.

(k) *Employer* has the same meaning as the term "employer" as defined in section 3(5) of the Employee Retirement Insurance Security Act of 1974.

(l) *Health insurance issuer* has the same meaning as the term "health insurance issuer" as defined in section 2791 of the Public Health Service Act.

(m) *Medical society* means a nonprofit organization or association that provides unified representation and advocacy for physicians at the national or state level and whose membership is comprised of a majority of physicians.

(n) *Hospital association* means a nonprofit organization or association that provides unified representation and advocacy for hospitals or health systems at a national, state, or local level and whose membership is comprised of a majority of hospitals and health systems.

(o) *Healthcare Provider and/or Supplier Association* means a nonprofit organization or association that provides unified representation and advocacy for providers and suppliers at the national or state level and whose membership is comprised of a majority of suppliers or providers.

(p) *State Entity* means any office, department, division, bureau, board, commission, agency, institution, or committee within the executive branch of a state government.

(q) *Combined data* means, at a minimum, a set of CMS claims data provided under this subpart combined with claims data, or a subset of claims data from at least one of the other claims data sources described in § 401.707(d).

(r) *Patient* means an individual who has visited the provider or supplier for

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a face-to-face or telehealth appointment at least once in the past 24 months.

(s) *Marketing* means the same as the term “marketing” at 45 CFR 164.501 without the exception to the bar for “consent” based marketing.

(t) *Violation* means a failure to comply with a requirement of a CMS DUA (CMS data use agreement) or QE DUA (qualified entity data use agreement).

(u) *Required by law* means the same as the phrase “required by law” at 45 CFR 164.103.

[76 FR 76567, Dec. 7, 2011, as amended at 81 FR 44479, July 7, 2016]

§ 401.705 Eligibility criteria for qualified entities.

(a) *Eligibility criteria*: To be eligible to apply to receive data as a qualified entity under this subpart, an applicant generally must demonstrate expertise and sustained experience, defined as 3 or more years, in the following three areas, as applicable and appropriate to the proposed use:

(1) Organizational and governance criteria, including:

(i) Expertise in the areas of measurement that they propose to use in accurately calculating quality, and efficiency, effectiveness, or resource use measures from claims data, including the following:

(A) Identifying an appropriate method to attribute a particular patient’s services to specific providers and suppliers.

(B) Ensuring the use of approaches to ensure statistical validity such as a minimum number of observations or minimum denominator for each measure.

(C) Using methods for risk-adjustment to account for variations in both case-mix and severity among providers and suppliers.

(D) Identifying methods for handling outliers.

(E) Correcting measurement errors and assessing measure reliability.

(F) Identifying appropriate peer groups of providers and suppliers for meaningful comparisons.

(ii) A plan for a business model that is projected to cover the costs of performing the required functions, including the fee for the data.

(iii) Successfully combining claims data from different payers to calculate performance reports.

(iv) Designing, and continuously improving the format of performance reports on providers and suppliers.

(v) Preparing an understandable description of the measures used to evaluate the performance of providers and suppliers so that consumers, providers and suppliers, health plans, researchers, and other stakeholders can assess performance reports.

(vi) Implementing and maintaining a process for providers and suppliers identified in a report to review the report prior to publication and providing a timely response to provider and supplier inquiries regarding requests for data, error correction, and appeals.

(vii) Establishing, maintaining, and monitoring a rigorous data privacy and security program, including disclosing to CMS any inappropriate disclosures of beneficiary identifiable information, violations of applicable federal and State privacy and security laws and regulations for the preceding 10-year period (or, if the applicant has not been in existence for 10 years, the length of time the applicant has been an organization), and any corrective actions taken to address the issues.

(viii) Accurately preparing performance reports on providers and suppliers and making performance report information available to the public in aggregate form, that is, at the provider or supplier level.

(2) Expertise in combining Medicare claims data with claims data from other sources, including demonstrating to the Secretary’s satisfaction that the claims data from other sources that it intends to combine with the Medicare data received under this subpart address the methodological concerns regarding sample size and reliability that have been expressed by stakeholders regarding the calculation of performance measures from a single payer source.

(3) Expertise in establishing, documenting and implementing rigorous data privacy and security policies including enforcement mechanisms.

(b) *Source of expertise and experience*: An applicant may demonstrate expertise and experience in any or all of the