

(i) *Factors for consideration for removal of quality measures.* CMS will weigh whether to remove measures based on the following factors:

(A) *Factor 1.* Measure performance among REHs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (“topped-out” measures);

(B) *Factor 2.* Performance or improvement on a measure does not result in better patient outcomes;

(C) *Factor 3.* A measure does not align with current clinical guidelines or practice;

(D) *Factor 4.* The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic;

(E) *Factor 5.* The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic;

(F) *Factor 6.* The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic;

(G) *Factor 7.* Collection or public reporting of a measure leads to negative unintended consequences other than patient harm; and

(H) *Factor 8.* The costs associated with a measure outweigh the benefit of its continued use in the program.

(ii) *Criteria to determine topped-out measures.* For the purposes of the REHQR Program, a measure is considered to be topped-out under paragraph (e)(3)(i)(A) of this section when it meets both of the following criteria:

(A) Statistically indistinguishable performance at the 75th and 90th percentiles (defined as when the difference between the 75th and 90th percentiles for an REH’s measure is within two times the standard error of the full data set); and

(B) A truncated coefficient of variation less than or equal to 0.10.

(iii) *Application of measure removal factors.* The benefits of removing a measure from the REHQR Program will be assessed on a case-by-case basis. Under this case-by-case approach, a measure will not be removed solely on the basis of meeting any specific factor.

(f) *Public reporting of data under the REHQR Program.* Data that an REH submits for the REHQR Program will be made publicly available on a CMS website in an easily understandable format after providing the REH an opportunity to review the data to be made public. CMS will publicly display REH data by the CCN when data are submitted under the CCNs.

(g) *Exception.* CMS may grant an exception to one or more data submission deadlines and requirements in the event of extraordinary circumstances beyond the control of the hospital, such as when an act of nature affects an entire region or locale or a systemic problem with one of CMS’ data collection systems directly or indirectly affects data submission. CMS may grant an exception as follows:

(1) *Upon request by the REH.* Specific requirements for submission of a request for an exception are available on a CMS website.

(2) *At the discretion of CMS.* CMS may grant exceptions to REHs that have not requested them when CMS determines that an extraordinary circumstance has occurred.

[88 FR 82181, Nov. 22, 2023]

PART 420—PROGRAM INTEGRITY: MEDICARE

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

SOURCE: 44 FR 31142, May 30, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 420.1 Scope and purpose.

This part sets forth requirements for Medicare providers, intermediaries, and carriers to disclose ownership and control information. It also deals with access to records pertaining to certain contracts entered into by Medicare providers. These rules are aimed at protecting the integrity of the Medicare program. The statutory basis for these requirements is explained in each of the other subparts.

[51 FR 34787, Sept. 30, 1986]

§ 420.3 Other related regulations.

(a) *Appeals procedures.* Part 498 of this chapter sets forth the appeals procedures available to providers whose provider agreements CMS terminates for failure to comply with the disclosure of information requirements set forth in subpart C of this part.

(b) *Exclusion, termination, or suspension.* Part 1001 of this title sets forth the rules applicable to exclusion, termination, or suspension from the Medicare program because of fraud or abuse

or conviction of program-related crimes.

[51 FR 34787, Sept. 30, 1986, as amended at 52 FR 22454, June 12, 1987]

Subpart B [Reserved]

Subpart C—Disclosure of Ownership and Control Information

§ 420.200 Purpose.

This subpart implements sections 1124, 1124A, 1126, and 1861(v)(1)(i) of the Social Security Act. It sets forth requirements for providers, Part B suppliers, intermediaries, and carriers to disclose ownership and control information and the identities of managing employees. It also sets forth requirements for disclosure of information about a provider's or Part B supplier's owners, those with a controlling interest, or managing employees convicted of criminal offenses against Medicare, Medicaid, or the title V (Maternal and Child Health Services) and title XX (Social Services) programs.

[57 FR 27306, June 18, 1992, as amended at 60 FR 50442, Sept. 29, 1995]

§ 420.201 Definitions.

As used in this subpart unless the context indicates otherwise:

Agent means any person who has been delegated the authority to obligate or act on behalf of a provider.

Disclosing entity means:

(1) A provider of services, an independent clinical laboratory, a renal disease facility, a rural health clinic, a Federally qualified health center, or a health maintenance organization (as defined in section 1301(a) of the Public Health Service Act);

(2) A carrier or other agency or organization that is acting for one or more providers of services for purposes of part A and part B of Medicare; and

(3) A part B supplier, as defined in § 400.202 of this chapter.

Group of practitioners means two or more health care practitioners who practice their profession at a common location (whether or not they share common facilities, common supporting staff, or common equipment).

Indirect ownership interest means any ownership interest in an entity that

has an ownership interest in the disclosing entity. The term includes an ownership interest in any entity that has an indirect ownership interest in the disclosing entity.

Managing employee means a general manager, business manager, administrator, director, or other individual that exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operation of the institution, organization, or agency, either under contract or through some other arrangement, whether or not the individual is a W-2 employee.

Other disclosing entity means any other Medicare disclosing entity and any entity that does not participate in Medicare, but is required to disclose certain ownership and control information because of participation in any of the programs established under title V, XIX, or XX of the Act. This includes:

(1) An entity (other than an individual practitioner or group of practitioners) that furnishes, or arranges for the furnishing of, items or services for which payment may be claimed by the entity under any plan or program established under title V of the Social Security Act or under an approved State Medicaid plan;

(2) An entity (other than an individual practitioner or group of practitioners) that furnishes, or arranges for the furnishing of, health-related services for which payment may be claimed by the entity under an approved State plan and services program under title XX of the Act; or

(3) A Medicaid fiscal agent.

Ownership interest means the possession of equity in the capital, the stock, or the profits of the disclosing entity.

Person with an ownership or control interest means a person or corporation that—

(1) Has an ownership interest totaling 5 percent or more in a disclosing entity;

(2) Has an indirect ownership interest equal to 5 percent or more in a disclosing entity;

(3) Has a combination of direct and indirect ownership interests equal to 5 percent or more in a disclosing entity;

(4) Owns an interest of 5 percent or more in any mortgage, deed of trust,

note, or other obligation secured by the disclosing entity if that interest equals at least 5 percent of the value of the property or assets of the disclosing entity;

(5) Is an officer or director of a disclosing entity that is organized as a corporation; or

(6) Is a partner in a disclosing entity that is organized as a partnership.

Significant business transaction means any business transaction or series of transactions during any one fiscal year, the total of which exceeds the lesser of \$25,000 and 5 percent of the total operating expenses of the provider.

Subcontractor means—

(1) An individual, agency, or organization to which a disclosing entity has contracted or delegated some of its management functions or responsibilities of providing medical care to its patients; or

(2) An individual, agency, or organization with which an intermediary or carrier has entered into a contract, agreement, purchase order or lease (or leases of real property) to obtain space, supplies, equipment, or services provided under the Medicare agreement.

Wholly owned supplier means a supplier whose total ownership interest is held by a provider or by a person, persons, or other entity with an ownership or control interest in a provider.

[44 FR 41642, July 17, 1979, as amended at 57 FR 24982, June 12, 1992; 57 FR 27306, June 18, 1992; 57 FR 35760, Aug. 11, 1992; 71 FR 20775, Apr. 21, 2006]

§ 420.202 Determination of ownership or control percentages.

(a) *Indirect ownership interest.* The amount of indirect ownership interest is determined by multiplying the percentages of ownership in each entity. For example, if A owns 10 percent of the stock in a corporation that owns 80 percent of the disclosing entity, A's interest equates to an 8 percent indirect ownership interest in the disclosing entity and must be reported. Conversely, if B owns 80 percent of the stock of a corporation that owns 5 percent of the stock of the disclosing entity, B's interest equates to a 4 percent indirect ownership interest in the disclosing entity and need not be reported.

(b) *Person with an ownership or control interest.* In order to determine the percentage of ownership interest in any mortgage, deed of trust, note, or other obligation, the percentage of interest owned in obligation is multiplied by the percentage of the disclosing entity's assets used to secure the obligation. For example, if A owns 10 percent of a note secured by 60 percent of the provider's assets, A's interest in the provider's assets equates to 6 percent and must be reported. Conversely, if B owns 40 percent of a note secured by 10 percent of the provider's assets, B's interest in the provider's assets equates to 4 percent and need not be reported.

§ 420.203 Disclosure of hiring of intermediary's former employees.

A provider must notify the Secretary promptly if it, or its home office (in the case of a chain organization), employs or obtains the services of an individual who, at any time during the year preceding such employment, was employed in a managerial, accounting, auditing, or similar capacity by an agency or organization which currently serves, or at any time during the preceding year, served as a Medicare fiscal intermediary or carrier for the provider. *Similar capacity* means the performance of essentially the same work functions as those of a manager, accountant, or auditor even though the individual is not so designated by title.

§ 420.204 Principals convicted of a program-related crime.

(a) *Information required.* Prior to CMS's acceptance of a provider agreement or issuance or reissuance of a supplier billing number, or at any time upon written request by CMS, the provider or part B supplier must furnish CMS with the identity of any person who:

- (1) Has an ownership or control interest in the provider or part B supplier;
- (2) Is an agent or managing employee of the provider or part B supplier; or
- (3) Is a person identified in paragraph (a)(1) or (a)(2) of this section and has been convicted of, or was an owner of, had a controlling interest in, or was a managing employee of a corporation that has been convicted of a criminal offense, subjected to any civil mone-

tary penalty, or excluded from the programs for any activities related to involvement in the Medicare, Medicaid, title V or title XX social services program, since the inception of those programs.

(b) *Refusal to enter into or renew agreement or to issue or reissue billing numbers.* CMS may refuse to enter into or renew an agreement with a provider of services, or to issue or reissue a billing number to a part B supplier, if any person who has an ownership or control interest in the provider or supplier, or who is an agent or managing employee, has been convicted of a criminal offense or subjected to any civil penalty or sanction related to the involvement of that person in Medicare, Medicaid, title V or title XX social services programs. In making this decision, CMS considers the facts and circumstances of the specific case, including the nature and severity of the crime, penalty or sanction and the extent to which it adversely affected beneficiaries and the programs involved. CMS also considers whether it has been given reasonable assurance that the person will not commit any further criminal or civil offense against the programs.

(c) *Notification of Inspector General.* CMS promptly notifies the Inspector General of the Department of the receipt of any application or request for participation, certification, re-certification, or for a billing number that identifies any person described in paragraph (a)(3) of this section and the action taken on that application or request.

[57 FR 27306, June 18, 1992]

§ 420.205 Disclosure by providers and part B suppliers of business transaction information.

A provider or part B supplier must submit to CMS, within 35 days after the date of a written request, full and complete information on—

(a) The ownership of a subcontractor with which the provider or part B supplier has had, during the previous 12 months, business transactions in an aggregate amount in excess of \$25,000;

(b) Any significant business transactions between the provider or part B supplier and any wholly owned supplier