

days after the date CMS receives the endorsed sponsor's notice of intent to terminate.

(e) *Termination by mutual consent.* (1) A contract may be modified or terminated at any time by written mutual consent.

(2) If the contract is terminated by mutual consent, the endorsed sponsor must provide notice to its discount card enrollees as provided in paragraph (d)(2) of this section.

(3) If the contract is modified by mutual consent, the endorsed sponsor must provide notice to its discount card enrollees of any changes that CMS determines are appropriate for notification within timeframes specified by CMS.

(f) *Appeal of contract determinations—* (1) *Scope.* This section establishes the procedures for reviewing the following contract determinations:

(i) A determination that an applicant is not qualified to enter into a contract with CMS under section 1860D–31 of the Act; and

(i) A determination to terminate a contract with an endorsed sponsor in accordance with paragraph (c) of this section.

(2) *Notice of determination.* When CMS makes an initial contract determination, it gives the endorsed sponsor or applicant written notice specifying—

(i) The reasons for the determination; and

(ii) The endorsed sponsor's or applicant's right to request reconsideration.

(3) *Effect of contract determination.* The contract determination is final and binding unless a timely request for a reconsideration hearing is filed under this section.

(4) *Right to reconsideration.* An endorsed sponsor whose contract is terminated or an applicant denied endorsement may request a hearing for reconsideration of the CMS contract determination.

(5) *Method and place for filing a request.* A request for a reconsideration hearing must be made in writing and filed with the CMS Central Office.

(6) *Time for filing a request.* The request for a reconsideration hearing must be filed within 15 days from the date of the notice of the initial determination.

(7) *Appointment of hearing officer.* CMS shall appoint a hearing officer to conduct the reconsideration. The hearing officer shall be a representative of the Administrator and not otherwise a party to the contract determination.

(8) *Conduct of hearing.* The endorsed sponsor or applicant may be represented by counsel and may present evidence and examine witnesses. A complete recording of the proceedings will be made and transcribed.

(9) *Reconsideration determination.* A reconsideration determination is a new determination that—

(i) Is based on a review of the contract determination, the evidence and findings upon which it was based, and any other written evidence submitted before notice of the reconsidered determination is mailed, including facts relating to the status of the endorsed sponsor subsequent to the contract determination; and

(ii) Affirms, reverses, or modifies the initial contract determination.

(10) *Notice of reconsidered determination.* As soon as practicable after the close of the hearing, the hearing officer issues a written reconsideration determination that contains the following:

(i) Findings with respect to the applicant's qualifications to enter into or an endorsed sponsor's qualifications to remain under a contract with CMS under section 1860D–31 of the Act;

(ii) A statement of the specific reasons for the reconsidered determination.

(11) *Effect of reconsidered determination.* A reconsidered determination is final and binding on the parties and is not subject to judicial review.

(g) *Compliance with HIPAA.* Failure of an endorsed sponsor to comply with HIPAA and/or the standards, implementation specifications, and requirements in 45 CFR parts 160, 162, and 164, as established in §403.812, shall be a violation of HIPAA and may be enforced under sections 1176 and 1177 of the Act.

**§ 403.822 Reimbursement of transitional assistance and associated sponsor requirements.**

(a) A Transitional Assistance Account is created within the Federal Supplementary Medical Insurance

Trust Fund and kept separate from all other funds within that fund.

(b) The Managing Trustee of the Transitional Assistance Account shall pay on a monthly basis from the Account the amounts certified by CMS as necessary to make payments for transitional assistance as allowed in § 403.808.

(c) Endorsed sponsors must routinely account to CMS for the transitional assistance provided to the transitional assistance enrollees for finalized (not pending, or denied) claims up to the allowed balance provided by CMS to the sponsor.

(d) Payment transactions will be audited by the Secretary or his agent.

(e) Federal funding in excess of the amount of the balance included in CMS's system is not permitted.

### Subpart I—Transparency Reports and Reporting of Physician Ownership or Investment Interests

SOURCE: 78 FR 9521, Feb. 8, 2013, unless otherwise noted.

#### § 403.900 Purpose and scope.

The regulations in this subpart implement section 1128G of the Act. These regulations apply to applicable manufacturers and applicable group purchasing organizations and describe the requirements and procedures for applicable manufacturers to report payments or other transfers of value provided to covered recipients, as well as for applicable manufacturers and applicable group purchasing organizations to report ownership or investment interests held by physicians or immediate family members of physicians in such entities.

#### § 403.902 Definitions.

For purposes of this subpart, the following definitions apply:

*Applicable group purchasing organization* means an entity that:

- (1) Operates in the United States; and
- (2) Purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities,

but not solely for use by the entity itself.

*Applicable manufacturer* means an entity that is operating in the United States and that falls within one of the following categories:

- (1) An entity that is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply, but not if such covered drug, device, biological or medical supply is solely for use by or within the entity itself or by the entity's own patients. This definition does not include distributors or wholesalers (including, but not limited to, repackagers, relabelers, and kit assemblers) that do not hold title to any covered drug, device, biological or medical supply.
- (2) An entity under common ownership with an entity in paragraph (1) of this definition, which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply.

*Assistance and support* means providing a service or services that are necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply.

*Certified nurse midwife* means a registered nurse who has successfully completed a program of study and clinical experience meeting guidelines prescribed by the Secretary, or has been certified by an organization recognized by the Secretary.

*Certified registered nurse anesthetist* means a certified registered nurse anesthetist licensed by the State who meets such education, training, and other requirements relating to anesthesia services and related care as the Secretary may prescribe. In prescribing such requirements the Secretary may use the same requirements as those established by a national organization for the certification of nurse anesthetists. Such term also includes, as prescribed by the Secretary, an anesthesiologist assistant.