

§ 403.822

(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

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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