§ 149.500

(e) The sponsor is responsible for ensuring that the records are maintained and provided according to this subpart.

Subpart F—Appeals

§149.500 Appeals.

- (a) An adverse reimbursement determination is final and binding unless appealed pursuant to paragraph (e) of this section.
- (b) Except as provided in paragraph (c) of this section, a sponsor may request an appeal of an adverse reimbursement determination.
- (c) A sponsor may not appeal an adverse reimbursement determination if the denial is based on the unavailability of funds.
- (d) An adverse reimbursement determination is a determination constituting a complete or partial denial of a reimbursement request.
- (e) If a sponsor appeals an adverse reimbursement determination, the sponsor must submit the appeal in writing to the Secretary within 15 calendar days of receipt of the determination pursuant to guidance issued by the Secretary.

§ 149.510 Content of request for appeal.

The request for appeal must specify the findings or issues with which the sponsor disagrees and the reasons for the disagreements. The request for appeal may include supporting documentary evidence the sponsor wishes the Secretary to consider.

§149.520 Review of appeals.

- (a) In conducting review of the appeal, the Secretary reviews the appeal, the evidence and findings upon which the adverse reimbursement determination was made, and any other written evidence submitted by the sponsor or the Secretary's designee and will provide a ruling on the appeal request.
- (b) In conducting the review, the Secretary reviews the determination at issue, the evidence and findings upon which it was based, any written documents submitted to the Secretary by the sponsor and the Secretary's designee, and determines whether to uphold, reverse or modify the Secretary's initial reimbursement determination.

- (c) A decision by the Secretary under this provision is final and binding.
- (d) Regardless of the Secretary's decision, additional reimbursement is contingent upon the availability of funds at the time of the Secretary's determination.
- (e) The Secretary informs the sponsor and the applicable Secretary's designee of the decision. The Secretary sends a written decision to the sponsor or the applicable Secretary's designee upon request.

Subpart G—Disclosure of Data Inaccuracies

§149.600 Sponsor's duty to report data inaccuracies.

A sponsor is required to disclose any data inaccuracies upon which a reimbursement determination is made, including inaccurate claims data and negotiated price concessions, in a manner and at a time specified by the Secretary in guidance.

§ 149.610 Secretary's authority to reopen and revise a reimbursement determination.

- (a) The Secretary may reopen and revise a reimbursement determination upon the Secretary's own motion or upon the request of a sponsor:
- (1) Within 1 year of the reimbursement determination for any reason.
- (2) Within 4 years of a reimbursement determination for good cause.
- (3) At any time, in instances of fraud or similar fault.
- (b) For purposes of this section, the Secretary does not find good cause if the only reason for the revision is a change of legal interpretation or administrative ruling upon which the determination to reimburse was made.
- (c) A decision by the Secretary not to revise a reimbursement determination is final and binding (unless fraud or similar fault is found) and cannot be appealed.

Subpart H—Change of Ownership Requirements

§149.700 Change of ownership requirements.

(a) Change of ownership consists of: (1) Partnership. The removal, addition, or