of this chapter and report the matter to the HHS Inspector General; or

(2) Issue initial denial determinations for those claims it is unable to review, make the determination that financial liability will be assigned to the health care facility, and report the matter to the HHS Inspector General.

(b) If a QIO provides a facility with sufficient notice and a reasonable amount of time to respond to a request for information about a claim, and if the facility does not respond in a timely manner, the QIO will deny the claim.

§ 476.93 Opportunity to discuss proposed initial denial determination and changes as a result of a DRG validation.

Before a QIO reaches an initial denial determination or makes a change as a result of a DRG validation, it must—

(a) Promptly notify the provider or supplier and the patient’s attending physician (or other attending health care practitioner) of the proposed determination or DRG change; and

(b) Afford an opportunity for the provider or supplier and the physician (or other attending health care practitioner) to discuss the matter with the QIO physician advisor and to explain the nature of the patient’s need for health care services, including all factors which preclude treatment of the patient as an outpatient or in an alternative level of inpatient care.

§ 476.94 Notice of QIO initial denial determination and changes as a result of a DRG validation.

(a) Notice of initial denial determination—

(1) Parties to be notified. A QIO must provide written notice of an initial denial determination to—

(i) The patient, or if the patient is expected to be unable to comprehend the notice, the patient’s next of kin, guardian or other representative or sponsor; (ii) The attending physician, or other attending health care practitioner; (iii) The facility; and (iv) The fiscal intermediary or carrier.

(2) Timing of the notice. The notice must be delivered to beneficiaries in the facility or mailed to those no longer in the facility, within the following time periods—

(i) For admission, on the first working day after the initial denial determination; (ii) For continued stay (e.g., outliers in facilities under a prospective payment system), by the first working day after the initial denial determination if the beneficiary is still in the facility, and within 3 working days if the beneficiary has been discharged; (iii) For preprocedure review, before the procedure is performed; (iv) For preadmission review, before admission; (v) If identification as a Medicare program patient has been delayed, within three working days of identification; (vi) For retrospective review, (excluding DRG validation and post procedure review), within 3 working days of the initial denial determination; and (vii) For post-procedure review, within 3 working days of the initial denial determination.

(3) Preadmission review. In the case of preadmission review, the QIO must document that the patient and the facility received notice of the initial denial determination.

(b) Notice of changes as a result of a DRG validation. The QIO must notify the provider and practitioner of changes to procedural and diagnostic information that result in a change of DRG assignment, within 30 days of the QIO’s decision.

(c) Content of the notice. The notice must be understandable and written in plain English and must contain—

(1) The reason for the initial denial determination or change as a result of the DRG validation; (2) For day outliers in hospitals, the date on which the stay or services in the facility will not be approved as being reasonable and medically necessary or appropriate to the patients’ health care needs; (3) A statement informing each party or his or her representative of the right to request in accordance with the provisions of part 473, subpart B of this chapter—

(i) Review of a change resulting from DRG validation; or (ii) Reconsideration of the initial denial determination;
§ 476.96 Review period and reopening of initial denial determinations and changes as a result of DRG validations.

(a) General timeframe. A QIO or its subcontractor—
(1) Within one year of the date of the claim containing the service in question, may review and deny payment; and
(2) Within one year of the date of its decision, may reopen an initial denial determination or a change as a result of a DRG validation.

(b) Extended timeframes. (1) An initial denial determination or change as a result of a DRG validation may be made after one year but within four years of the date of the claim containing the service in question, if CMS approves.
(2) A reopening of an initial denial determination or change as a result of a DRG validation may be made after one year but within four years of the date of the QIO’s decision if—
(1) Additional information is received on the patient’s condition;
(2) Reviewer error occurred in interpretation or application of Medicare coverage policy or review criteria;
(3) There is an error apparent on the face of the evidence upon which the initial denial or DRG validation was based; or
(4) There is a clerical error in the statement of the initial denial determination or change as a result of a DRG validation.

§ 476.98 Reviewer qualifications and participation.

(a) Peer review by physician. (1) Except as provided in paragraph (a)(2) of this section, each person who makes an initial denial determination about services furnished or proposed to be furnished by a licensed doctor of medicine or osteopathy or by a doctor of dentistry must be respectively another licensed doctor of medicine or osteopathy or of dentistry with active staff privileges in one or more hospitals in the QIO area.
(2) If a QIO determines that peers are not available to make initial denial determinations, a doctor of medicine or osteopathy may make denial determinations for services ordered or performed by a doctor in any of the three specialties.
(3) For purposes of paragraph (a)(1) of this section, individuals authorized to practice medicine in American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands as “medical officers” may make determinations on care ordered or furnished by their peers but not on care ordered or furnished by licensed doctors of medicine or osteopathy.