

**§ 466.94 Notice of PRO initial denial determination and changes as a result of a DRG validation.**

(a) *Notice of initial denial determination*—(1) *Parties to be notified.* A PRO 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 PRO 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 PRO 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 PRO'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;
- (4) The locations for filing a request for reconsideration or review and the time period within which a request must be filed;
- (5) A statement about who is liable for payment of the denied services under section 1879 of the Act; and
- (6) A statement concerning the duties and functions of the PRO under the Act.

(d) *Notice to payers.* The PRO must provide prompt written notice of an initial denial determination or changes as a result of a DRG validation to the Medicare fiscal intermediary or carrier within the same time periods as the notices to the other parties.

(e) *Record of initial denial determination and changes as a result of a DRG validation.* (1) The PRO must document and preserve a record of all initial denial determinations and changes as a result of DRG validations for six years from the date the services in question were provided.

(2) The documentary record must include—

- (i) The detailed basis for the initial denial determination or changes as a result of a DRG validation; and
- (ii) A copy of the determination or change in DRG notices sent to all parties and identification of each party and the date on which the notice was mailed or delivered.