

(2) *Isolated deficiencies.* A facility is not required to submit a plan of correction when it has deficiencies that are isolated and have a potential for minimal harm, but no actual harm has occurred.

(e) *Disagreement regarding remedies.* If the State and CMS disagree on the decision to impose a remedy, the disagreement is resolved in accordance with § 488.452.

(f) *Notification requirements*—(1) Except when the State is taking action against a non-State operated NF, CMS or the State (as authorized by CMS) gives the provider notice of the remedy, including the—

- (i) Nature of the noncompliance;
- (ii) Which remedy is imposed;
- (iii) Effective date of the remedy; and
- (iv) Right to appeal the determination leading to the remedy.

(2) When a State is taking action against a non-State operated NF, the State's notice must include the same information required by CMS in paragraph (f)(1) of this section.

(3) *Immediate jeopardy—2 day notice.* Except for civil money penalties and State monitoring imposed when there is immediate jeopardy, for all remedies specified in § 488.406 imposed when there is immediate jeopardy, the notice must be given at least 2 calendar days before the effective date of the enforcement action.

(4) *No immediate jeopardy—15 day notice.* Except for civil money penalties and State monitoring, notice must be given at least 15 calendar days before the effective date of the enforcement action in situations in which there is no immediate jeopardy.

(5) *Date of enforcement action.* The 2- and 15-day notice periods begin when the facility receives the notice.

(6) *Civil money penalties.* For civil money penalties, the notices must be given in accordance with the provisions of §§ 488.434 and 488.440.

(7) *State monitoring.* For State monitoring, no prior notice is required.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995, as amended at 64 FR 13360, Mar. 18, 1999]

#### § 488.404 Factors to be considered in selecting remedies.

(a) *Initial assessment.* In order to select the appropriate remedy, if any, to apply to a facility with deficiencies, CMS and the State determine the seriousness of the deficiencies.

(b) *Determining seriousness of deficiencies.* To determine the seriousness of the deficiency, CMS considers and the State must consider at least the following factors:

(1) Whether a facility's deficiencies constitute—

- (i) No actual harm with a potential for minimal harm;
- (ii) No actual harm with a potential for more than minimal harm, but not immediate jeopardy;
- (iii) Actual harm that is not immediate jeopardy; or
- (iv) Immediate jeopardy to resident health or safety.

(2) Whether the deficiencies—

- (i) Are isolated;
- (ii) Constitute a pattern; or
- (iii) Are widespread.

(c) *Other factors which may be considered in choosing a remedy within a remedy category.* Following the initial assessment, CMS and the State may consider other factors, which may include, but are not limited to the following:

- (1) The relationship of the one deficiency to other deficiencies resulting in noncompliance.
- (2) The facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies.

#### § 488.406 Available remedies.

(a) *General.* In addition to the remedy of termination of the provider agreement, the following remedies are available:

- (1) Temporary management.
- (2) Denial of payment including—
  - (i) Denial of payment for all individuals, imposed by CMS, to a—
    - (A) Skilled nursing facility, for Medicare;
    - (B) State, for Medicaid; or
  - (ii) Denial of payment for all new admissions.
- (3) Civil money penalties.
- (4) State monitoring.
- (5) Transfer of residents.
- (6) Closure of the facility and transfer of residents.

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- (7) Directed plan of correction.
- (8) Directed in-service training.
- (9) Alternative or additional State remedies approved by CMS.

(b) *Remedies that must be established.* At a minimum, and in addition to termination of the provider agreement, the State must establish the following remedies or approved alternatives to the following remedies:

- (1) Temporary management.
- (2) Denial of payment for new admissions.
- (3) Civil money penalties.
- (4) Transfer of residents.
- (5) Closure of the facility and transfer of residents.
- (6) State monitoring.

(c) *State plan requirement.* If a State wishes to use remedies for noncompliance that are either additional or alternative to those specified in paragraphs (a) or (b) of this section, it must—

- (1) Specify those remedies in the State plan; and
- (2) Demonstrate to CMS's satisfaction that those remedies are as effective as the remedies listed in paragraph (a) of this section, for deterring noncompliance and correcting deficiencies.

(d) *State remedies in dually participating facilities.* If the State's remedy is unique to the State plan and has been approved by CMS, then that remedy, as imposed by the State under its Medicaid authority, may be imposed by CMS against the Medicare provider agreement of a dually participating facility.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

**§ 488.408 Selection of remedies.**

(a) *Categories of remedies.* In this section, the remedies specified in § 488.406(a) are grouped into categories and applied to deficiencies according to how serious the noncompliance is.

(b) *Application of remedies.* After considering the factors specified in § 488.404, as applicable, if CMS and the State choose to impose remedies, as provided in paragraphs (c)(1), (d)(1) and (e)(1) of this section, for facility noncompliance, instead of, or in addition to, termination of the provider agreement, CMS does and the State must follow the criteria set forth in para-

graphs (c)(2), (d)(2), and (e)(2) of this section, as applicable.

(c) *Category 1.* (1) Category 1 remedies include the following:

- (i) Directed plan of correction.
- (ii) State monitoring.
- (iii) Directed in-service training.

(2) CMS does or the State must apply one or more of the remedies in Category 1 when there—

- (i) Are isolated deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or
- (ii) Is a pattern of deficiencies that constitutes no actual harm with a potential for more than minimal harm but not immediate jeopardy.

(3) Except when the facility is in substantial compliance, CMS or the State may apply one or more of the remedies in Category 1 to any deficiency.

(d) *Category 2.* (1) Category 2 remedies include the following:

- (i) Denial of payment for new admissions.
- (ii) Denial of payment for all individuals imposed only by CMS.
- (iii) Civil money penalties of \$50–3,000 per day.
- (iv) Civil money penalty of \$1,000–\$10,000 per instance of noncompliance.

(2) CMS applies one or more of the remedies in Category 2, or, except for denial of payment for all individuals, the State must apply one or more of the remedies in Category 2 when there are—

- (i) Widespread deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or
- (ii) One or more deficiencies that constitute actual harm that is not immediate jeopardy.

(3) CMS or the State may apply one or more of the remedies in Category 2 to any deficiency except when—

- (i) The facility is in substantial compliance; or
- (ii) CMS or the State imposes a civil money penalty for a deficiency that constitutes immediate jeopardy, the penalty must be in the upper range of penalty amounts, as specified in § 488.438(a).

(e) *Category 3.* (1) Category 3 remedies include the following:

- (i) Temporary management.