

MEMORANDUM

Texas Department of Human Services * Long Term Care/Policy

TO: LTC-R Regional Directors
Section/Unit Managers

FROM: Marc Gold
Section Manager
Long Term Care-Policy
State Office MC: W-519

SUBJECT: Regional Survey & Certification Letter #99-11

DATE: April 7, 1999

The attached RS&C Letter is being provided to you for information purposes and should be shared with all professional staff. **A rule will be promulgated to implement the contents of this memo.**

- RS&C Letter No. 99-11 -- New Regulation on Per-Instance Civil Monetary Penalty for Nursing Homes; Call Beverly Tucker, Section Manager, Professional Services, at (512) 438-2631.

If you have any questions, please direct inquiries to the individuals or sections listed above.

~Original Signature on File~

Marc Gold

Attachment

DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Care Financing Administration

Region VI
1301 Young Street, Room 833
Dallas, Texas 75202

March 23, 1999

REGIONAL SURVEY AND CERTIFICATION LETTER NO: 99-11

To: All State Survey Agencies (Action)
All Title XIX Single State Agencies (Information)

Subject: New Regulation on Per-Instance Civil Monetary Penalty for Nursing Homes.

Enclosed is the Final Rule, with comment period, of the new regulation expanding the Civil Monetary Penalty options for Nursing Homes. This option permits imposition of a CMP for an instance of noncompliance. The effective date is May 17, 1999.

If you have any questions please call Dan McElroy at 214-767-6322.

Sincerely,

~Signature on File~

Daniel J. McElroy for Calvin Cline
Chief, Survey and Certification Operations Branch

Enclosure

Copr. (C) West 1999 No Claim to Orig. U.S. Govt. Works

| Citation | Rank (R) | Database | Mode |
|-------------------------------------------------------------------|----------|----------|------|
| 64 FR 13354-01 1999 WL 143479 (F.R.) (Cite as: 64 FR 13354) | R 1 OF 2 | FR | Page |

RULES and REGULATIONS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 488
[HCFA-2035-FC]
RIN 0938-AJ35

Medicare and Medicaid Programs; Civil Money Penalties for Nursing Homes (SNF/NF), Change in Notice Requirements, and Expansion of Discretionary Remedy Delegation

Thursday, March 18, 1999

*13354 AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period expands current Medicare and Medicaid regulations regarding the imposition of civil money penalties imposed on nursing homes that are not in compliance with program requirements. The existing regulations provide for the imposition of a civil money penalty in a specific amount for each day of noncompliance and provide further that the civil money penalty stays in place until the facility comes into substantial compliance with all participation requirements or the facility is terminated from participation in the program. This new rule adds the ability for HCFA or the State to impose a single civil money penalty amount for an instance of a nursing home's noncompliance. We are also deleting language to remove the requirement of a maximum notification period for imposition of a remedy.

DATES:

Effective date:

These regulations are effective on May 17, 1999.

Comment date: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on May 17, 1999.

ADDRESSES: Mail an original and 3 copies of written comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA-20350FC, P.O. Box 26585, Baltimore, MD 21207-0385.

If you prefer, you may deliver an original and 3 copies of your written comments to one of the following addresses: Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, D.C. 20201, or Room C5-09-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Comments may also be submitted electronically to the following e-mail address: HCFA205FC@hcfa.gov. For e-mail comment procedures, see the beginning of SUPPLEMENTARY INFORMATION. For further information on ordering copies of the Federal Register contained in this document, see the beginning of Supplementary Information.

FOR FURTHER INFORMATION:

E-mail, Comments, Procedures, and Availability of Copies

E-mail comments must include the full name and address of the sender, and must be submitted to the referenced address in order to be considered. All comments must be incorporated in the e-mail message because we may not be able to access attachments. Electronically submitted comments will be available for public inspection at the Independence Avenue address, below. Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA-2035-FC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309-G of the Department's offices at 200 Independence Avenue, SW, Washington, D.C., on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690-7890).

Copies: To order copies of the Federal Register containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512-1800 or by faxing to (202) 512-2250. The cost for each copy is \$8. As an alternative, you can view and photocopy the Federal Register document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the Federal Register.

This Federal Register document is also available from the Federal Register online database through GPO Access, a service of the U.S. Government Printing Office. Free public access is available on a Wide Area Information Server (WAIS) through the Internet and via asynchronous

dial-in. Internet users can access the database by using the World Wide Web; the Superintendent of Documents home page address is <http://www.access.gpo.gov/nara/>, by using local WAIS client software, or by telnet to swais.access.gpo.gov, then login as guest (no password required). Dial-in users should use communications software and modem to call (202) 512-1661; type swais, then login as guest (no password required).

I. Background

To participate in the Medicare and/or Medicaid programs, long-term care facilities must be certified as meeting Federal participation requirements. Long-term care facilities include skilled nursing facilities for Medicare and nursing facilities for Medicaid. The Federal participation requirements for these facilities are specified in the statute at sections 1819 and 1919 of the Social Security Act (the Act) and in implementing regulations at 42 CFR Part 483, Subpart B.

Section 1864(a) of the Act authorizes the Secretary to enter into agreements with State survey agencies to determine whether skilled nursing facilities meet the Federal participation requirements for Medicare. Section 1902(a)(33)(B) of the Act provides for State survey agencies to perform the same survey tasks for facilities participating or seeking to participate in the Medicaid program.

The results of these Medicare and Medicaid surveys are used by HCFA and the State Medicaid agency, respectively, as the basis for a decision *13355 to enter into, deny, or terminate a provider agreement with the facility. They are also used to determine whether one or more remedies should be imposed where noncompliance is identified.

To assess compliance with Federal participation requirements, surveyors conduct onsite inspections (surveys) of facilities. In the survey process, surveyors directly observe the actual provision of care and services to residents and the effect or possible effects of that care to assess whether the care provided meets the assessed needs of individual residents.

Among the remedies available to the Secretary and the States under the statute to address facility noncompliance is a civil money penalty. Authorized by sections 1819(h) and 1919(h) of the Act, civil money penalties may be imposed to remedy noncompliance at amounts not to exceed \$10,000 per day. The statute additionally permits the Secretary and the States to impose a civil money penalty for past instances of noncompliance even if a facility is in compliance at the time of a current survey. The Secretary is obliged to follow the procedures set out at section 1128A of the Act in processing these remedies.

The implementing regulations that govern the imposition of civil money penalties, as well as the other remedies authorized by the statute, were published on November 10, 1994 (59 FR 56116). The enforcement rules are set forth at 42 CFR Part 488, Subpart F, and the provisions directly affecting civil money penalties are set forth at 42 CFR 488.430 to 488.444. The final enforcement rule was indicative of more fundamental changes in the principles upon which the enforcement system is based. We implemented the Congress' mandate, as originally embodied in the Omnibus Budget Reconciliation Act of 1987, to abandon our hierarchical system of

requirements and to develop instead a system capable of detecting and responding to noncompliance with any requirement. The new system is built on the assumption that all requirements must be met and enforced and that requirements take on greater or lesser significance as a function of the circumstances and resident outcomes in the facility at the time of the survey. Thus, in the case of civil money penalties, facilities can expect to receive increased penalties as the nature and extent of their noncompliance increases. Current procedures allow for penalties to be assessed for \$3,050 per day up to \$10,000 per day for noncompliance that constitutes immediate jeopardy to patient health and safety, while penalties of \$50 to \$3,000 per day may be imposed where immediate jeopardy does not exist.

In addition, the regulations currently require multiple notices prior to imposition of remedies. One of the notification requirements contained at 42 CFR 488.402(f)(5) establishes a maximum number of days that may pass before a remedy must be imposed.

II. Provisions of the Final Rule with Comment

A. Latest date of enforcement action.

Regulations at 42 CFR 488.402(f)(5) establish a maximum time frame of 20 calendar days for HCFA or the State, as appropriate, to both notify a provider that remedies will be imposed and actually impose the remedy(ies). Establishment of a maximum time frame to accomplish both notice and imposition of remedies has proven to be problematic as well as unnecessarily restrictive for HCFA and the State. Briefly stated, this regulation requires that remedies must be imposed within 20 days of their notice to the provider and when they are not, HCFA or the State, as appropriate, must issue another notice. The purpose of providing notice is to assure an entity that it will be reasonably informed in advance of an adverse action of the factual and legal basis for that action. Such due process concerns have been satisfied for many years by providing nursing homes with at least 2 days' notice in immediate jeopardy cases and 15 days in all other cases. Since a provider is initially notified of the remedies to be imposed following the survey, establishing a maximum time of twenty days for a remedy to be imposed unnecessarily requires an additional notice.

By eliminating the maximum notice period, providers will receive no less prior notice than has traditionally been the case and, as importantly, would receive no less information than were the maximum notice period requirement to stay in effect. Thus, the only impact of the current rule has been to artificially delay enforcement actions when providers have already been well apprised of the grounds for the action in previous correspondence from either HCFA or the State, but HCFA or the State is unable to administratively impose the remedy(ices) within 20 days of that notice. That is not a sufficient reason to retain the requirement.

Therefore, §488.402(f)(5) will merely state that the 2- and 15-day notice periods begin when the facility receives the initial notice that a remedy is being imposed.

B. Per instance civil money penalties

When the civil money penalty provisions of the enforcement regulations were published four years ago, they reflected an interpretation of the statute that required HCFA and the States to make a determination of not only the beginning date of identified deficiencies, but an ending date as well. Where the beginning date of a deficiency could be determined, that date would signify the beginning of the provider's liability even if that date preceded the time of the survey that first surfaced the issue. When the beginning date of the deficiency could not be determined, the liability, for purposes of a civil money penalty, would be the date of the survey. Determining the ending date of the noncompliance, however, has at times proved to be more troublesome because it has required, most often, a revisit to the facility to document that the noncompliance has, in fact, been corrected. It has been an issue of some consequence between the provider industry and HCFA and States that survey teams have not returned to facilities as quickly as facilities might like in order to establish that noncompliance no longer exists. It has also been an issue to providers that civil money penalty liability has continued in many cases even where the originally identified deficiencies have been corrected, but new ones have arisen. This has occurred because providers must establish substantial compliance with all requirements to avoid civil money penalty liability, not just compliance with the deficiencies that triggered the decision to impose the penalty in the first place. At the same time, current utilization of our civil money penalty authority has been an issue with the consumer community because of what it perceives to be a less than fully effective enforcement tool. As relevant here, some consumers have expressed their belief that whatever the features are to the regulatory scheme that arguably slow the pace of enforcement, these features should be revised quickly to maximize the benefits conferred by the enforcement provisions of the statute.

Beyond this, under the enforcement scheme that HCFA and the States have followed, it has largely been the case that, except where immediate jeopardy has been involved or the provider has been found to be a poor performing facility, civil money penalties have not been imposed where facilities have been able to correct deficiencies before a predetermined date for the completion of corrections. As a result, we believe that many facilities have avoided the #13356 imposition of penalties although subsequent to achieving compliance these same facilities have failed to maintain substantial compliance. This phenomenon has, to some degree, perpetuated the problem posed by the so-called "you-you" facilities that were of concern to the Congress when it enacted nursing home reform as well as to the Institute of Medicine whose recommendations formed the basis for many of the changes now appearing in the statute. When the per instance civil money penalty is selected we do not envision a period to correct prior to imposition. As we have noted previously, many facilities have avoided the imposition of penalties because a period to correct has been provided and they have initially come into compliance but failed to maintain substantial compliance. Since the per instance civil money penalty will be used when noncompliance is documented, and the penalty does not accrue until substantial compliance is achieved, permitting a period to correct before imposing the penalty defeats the purpose of this remedy.

While we believe that the basic approach we have taken to the imposition of civil money penalties is still merited since we believe it has provided both a sentinel effect in discouraging facility noncompliance and has provided an effective response to facility noncompliance where it has been identified, we have concluded that the statute offers greater flexibility than we have

exercised up to now. Specifically, we believe the statute permits the Secretary and the States to focus on individual instances of noncompliance without having to track the duration of time that the facility remains out of compliance with those requirements (or with other program requirements). Thus, where sections 1819(h)(2)(B)(ii) and 1919(h)(2) of the Act provide that a civil money penalty may be imposed for up to \$10,000 for each day of noncompliance, it is entirely consistent with the statute that HCFA or a State impose a penalty for the noncompliance it identifies without regard to additional days of noncompliance that might yet be identified. Indeed, there is nothing in the statute that compels either us or the States to await a determination of the total number of days of noncompliance before having the authority to react to the noncompliance that has been identified. By statute, HCFA or the State may increase a civil money penalty to reflect additional days of noncompliance beyond those identified during the survey. However, this neither reflects an exclusive route to a civil money penalty liability nor establishes a necessary precondition to the triggering of this particular remedy. Not only do we derive this interpretation directly from the civil money penalty provisions of the statute, but we find support as well in the statute's broader mandate (at sections 1819(h)(2)(A) and 1919(h)(1) of the Act) that nothing in the enforcement provisions "shall be construed as restricting the remedies available to the Secretary [or the State] to remedy a skilled nursing facility's [or nursing facility's] deficiencies."

Thus, should a survey team identify a particular instance of noncompliance during a survey, such as the presence of an avoidable pressure sore in a facility resident, we believe the statute authorizes us or a State to impose an immediate civil money penalty for that one instance of noncompliance. The only limitation that the statute would provide is that the civil money penalty liability for that instance of noncompliance could not be more than \$10,000 for the day during which the noncompliance was identified.

On the other hand, HCFA or a State could identify several instances of noncompliance, perhaps relating to different aspects of facility obligations (as, for example, could be the case when deficiencies have been identified in areas of hydration, diet, resident assessment, and resident rights) and find itself imposing several different civil money penalties for each instance of noncompliance as long as the total facility liability did not exceed \$10,000 per day.

What we mean by an "instance" in this regulation is a single deficiency identified by the tag number used as a reference on the statement of deficiencies. While we consider an instance as a singular event of noncompliance, there can be more than one instance of noncompliance identified during a survey. For example, during the course of a survey, HCFA or a State may identify several instances of noncompliance, each in distinct regulatory areas such as resident rights (42 CAR 483.10) and quality of care (§483.25). If the noncompliance in the former area involves a violation of a resident's right to privacy, that instance of noncompliance might trigger a civil money penalty of \$1,000. If noncompliance with the latter requirement relates to an avoidable pressure sore, that instance of noncompliance might trigger a civil money penalty of \$4,000. The sum of these penalties, \$5,000, would be within the statutory limitation of \$10,000 specified by the statute for a facility's liability for any given day of noncompliance.

When considering whether a civil money penalty will be used as a remedy, the survey agency must also decide whether to establish the penalty on the basis of per day or per instance. This

regulation does not authorize the use of both. When compliance with Federal requirements is evaluated by the survey agency and a decision is reached to impose a civil money penalty, a concomitant decision must be made whether the civil money penalty will be used on a determination of per instance or per day.

Accordingly, we are adopting in this regulation the option of permitting the imposition of civil money penalties for each instances of noncompliance in addition to the option already set out in existing regulations to assess a civil money penalty for each day of noncompliance as long as the facility fails to achieve substantial compliance with all requirements.

Therefore, we are revising §488.408, Selection of remedies; §488.430, Civil money penalties: Basis for imposing penalty; §488.432, Civil money penalties: When penalty is collected; §488.434, Civil money penalties: Notice of penalty; §488.438, Civil money penalties: Amount of penalty; §488.440, Civil money penalties: Effective date and duration of penalty; §488.442, Civil money penalties: Due date for payment of penalty; and §488.454, Duration of remedies, to incorporate per instance civil money penalties to our procedures.

Since a per instance civil money penalty is not cumulative, we believe that a different calculus needs to be applied to better formulate amounts that may be imposed as penalties under this regulation. First, we are establishing a minimum of \$1,000 for a per instance civil money penalty. Because this penalty will not lap over to a second or successive days of noncompliance, we believe it is important that this penalty have a significant impact on noncompliant providers to encourage their compliance at the earliest possible date and to discourage similar conduct in the future. Were we to impose penalties in lower amounts, we do not believe the necessary incentive would be present. Additionally, we are not limiting penalty amounts (as we did in the already existing rule) depending on whether immediate jeopardy is present. First the statute does not distinguish between these two types of noncompliance in terms of determining an appropriate penalty amount. Second, because here, too, a per instance penalty would be a response to a specifically identified example of noncompliance *13357 that would provide for no penalty aggregation beyond the first day, we believe there needs to be an ability for HCFA and States to respond to egregious instances of noncompliance in a way that is commensurate with the seriousness that this type of violation represents.

Determination of the actual amount per instance will be governed by the following:

- Use of scope and severity (as that matrix has been applied under the existing enforcement rule) to assist in determining the magnitude of the noncompliance, including whether actual harm has occurred.
- The facility's degree of culpability.
- The facility's history of prior offenses, including repeat deficiencies.

These criteria are the same as those applied to determining penalty amounts under the current regulation.

The seriousness of the infraction should be apparent in the decision; e.g., an unnecessary death of a resident as a result of no active supervision presents a far different problem than does the infraction of finding that a confused person has been inappropriately attired or that a resident has not been given the proper privacy while receiving personal care from a caregiver. A

determination of the scope and severity of the infraction should occur before any determination of the amount of the per instance civil money penalty is made. Ultimately, the amount of money assigned to a per instance issue of noncompliance when compared to the problem, and whether the civil money penalty proves sufficient to provide a long term remedy, will have to withstand the test of reasonableness.

We do not expect these penalty determinations to be made with mathematical precision. As we have learned from our experience over the past few years, the determination of deficiencies (and decisions concerning an appropriate enforcement response) involve some degree of judgment. This is not only inevitable but desirable because patient care failings, for the most part, do not represent arithmetic deviations from a norm. Rather, they represent varying degrees of the many forms of harm that facility residents may experience. Our expectation is that, as a whole, what we will see in the implementation of this regulation is a pattern that generally associates more severe penalties as deficiencies pose greater harm or risks to residents' well-being. We expect to provide additional guidance and training to surveyors and others who will be asked to apply this regulation, and this guidance and training will reflect the approach taken in this regulation.

Under this additional option, a survey agency could recommend a per day penalty of not more than \$3,000 for non-immediate jeopardy violations (or not more than \$10,000 in cases of immediate jeopardy) for any documented period of noncompliance without having an obligation to determine the entire period of time that the noncompliance may be present. For example, a survey team enters a facility on June 1 and observes that a facility is not in substantial compliance. The team returns July 1 and determines that the noncompliance it initially identified has continued unabated. The survey agency could at that time recommend a penalty of up to \$3,000 per day (or \$10,000 in the case of immediate jeopardy) for each of the 30 days of noncompliance between June 1 and July 1. This would be the case even if the noncompliance might yet extend for additional days or weeks. Thus, the CMP in such a case would be based on the number of days of noncompliance actually identified without an affirmative obligation on HCFA's or the State's part to ascertain when, in fact, the noncompliance ceases to exist in order to calculate the penalty amount. Or, in another hypothetical situation, a survey team that enters a facility on June 1 may determine from facility records or other evidence that the facility has been out of compliance since May 15. The survey agency could then determine that there have been 15 days of noncompliance for this past period and recommend a penalty up to the regulatory maximum amounts for each of those days of noncompliance without regard to how much longer after June 1 the noncompliance may be present.

The new option would be intended to complement, not supplant, the current CMP authority and the new per instance CMP described above. Our goal in considering the adoption of this third option is to improve nursing home compliance in a way that does not require multiple revisits to impose but which also could have significant financial impact. The potential advantage of this new option over the current CMP authority is that a penalty can be imposed for documented violations without the requirement of multiple revisits by the survey team, in order to determine the amount of the CMP. Under current CMP authority, no penalty may be collected until an ending date for the noncompliance is determined. We believe this policy would serve to motivate a facility to provide care to its residents in a fully compliant manner that would enable it to avoid these potentially significant CMP's in the first place. If a facility were not to undertake its

responsibilities in this fashion, it would know in advance that there would be swift action taken to remedy noncompliant behavior.

The Department is especially interested in hearing from states, consumer groups, and providers as to whether they regard this additional type of penalty authority to be useful, and likely to enhance to objective of seeing nursing homes achieve substantial compliance on a sustained basis. We would also want to receive comments on whether this proposal would be administratively practical. Lastly, we encourage comments on whether there should be a maximum daily penalty amount established for this option other than what the statute already provides.

III. State Authorization to Initiate Notice-Notice of Policy Change

Regulations at §488.402(f)(1) currently permit States, as authorized by HCFA, to send notice of adverse actions to facilities which would otherwise be notified directly by HCFA. In the preamble of the Federal Register document that set forth this specific regulation (60 FR 50115, September 28, 1995), we discussed our intent to permit States to give notice of remedies, on behalf of HCFA, only in cases of minimal noncompliance. Limiting the State notification to situations of minimal noncompliance was based on our belief at the time that HCFA should be more directly involved in providing notice of remedies in cases of serious noncompliance.

Our experience has shown us that the current interpretation impedes our ability to respond as quickly as we would like to in instances of facility noncompliance because of the extra time that HCFA's direct involvement requires. Just as we retain responsibility for making decisions about the imposition of remedies for lesser degrees of noncompliance, so too we want to provide the same review, and retain the same responsibility, of cases that pose more serious examples of noncompliance before authorizing a State to impose remedies on our behalf. Thus, under the interpretation we are adopting here for §488.402(f)(1), States are authorized to impose any remedy which we have the authority to impose, but only as directed by HCFA. We *13358 expect that this adjustment to our process will result in the imposition of remedies in a more expeditious and efficient manner than has previously been the case.

IV. Response to Comments

Because of the large number of items of correspondence we normally receive on Federal Register documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the DATES section of this preamble, and, when we proceed with a subsequent document, we will respond to the major comments in the preamble to that document.

V. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the Federal Register and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however,

if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. We believe that dispensing with proposed rulemaking is in the public interest and, accordingly, are proceeding here directly with a final rule.

Residents of the nation's nursing homes are among the most vulnerable members of our society. Their well-being is entrusted completely to the caregivers with whom they come into contact at these facilities, and, in no small measure, they rely significantly on the machinery of Federal and State government to protect their interests through the enforcement mechanisms authorized by the Medicare and Medicaid statutes. We believe that the more diligent we are in our enforcement efforts, the greater the likelihood that facilities will be encouraged to comply with our requirements, and the greater the likelihood that facility residents will receive the kind of quality care that the statute envisions.

While we believe that we have made material progress in advancing the well-being of facility residents since the advent of nursing home reform, we know that there are opportunities to improve on our record. A report recently issued by the United States General Accounting Office (GAO), in which there was a focus on nursing home conditions, spoke of the continuing presence of unacceptable care in many facilities. Citing continuing problems with meeting some of the most basic needs of residents, such as hydration, nutrition, weight maintenance, and the avoidance of pressure sores, The GAO concluded that there was still important work to be done to make the enforcement scheme of the nursing home reform legislation as effective as it might be. The GAO made strong recommendations for HCFA to bolster its enforcement scheme in an effort to minimize, if not eliminate, the kinds of care problems it identified.

We are most troubled by these reports of poor care. We recognize the importance of making whatever adjustments we have the authority to make as swiftly as we reasonably can if we are to best protect resident well-being. Were we to subject these rules on the imposition of civil money penalties to the full course of proposed rulemaking before finalizing them, we believe we would lose valuable opportunities to respond to cases of noncompliance where the more rapid imposition of penalties would likely reduce the exposure of larger numbers of the nation's nursing home residents to substandard, and sometimes dangerous, levels of care. Because these rules would focus on specific instances of noncompliance, and would permit HCFA and the States to thereby focus swiftly on pinpointed unacceptable care practices, we believe it is in the public interest to make these rules effective at the earliest possible time. We believe additionally that where this rule is so reflective of what it is that the statute is aimed at, there is particular urgency to make these rules available quickly.

For similar reasons, we believe we have good cause to eliminate the requirement establishing a maximum time frame of 20 days to notify a provider of the imposition of remedies contained at §488.402(f)(5). Elimination of this maximum time frame does not eliminate the providers' right to notice in advance of an adverse action. Such due process continues to be satisfied with at least 2 days' notice in immediate jeopardy cases and 15 days in all other cases. The only impact of the current rule is to artificially delay enforcement actions when providers have already been well apprised of the grounds for the action in previous correspondence from either HCFA or the State. Again, we believe it is in the public interest to make this rule change effective at the earliest

possible time and dispense with the full course of proposed rulemaking.

In the case of the change to our interpretation of 42 CFR 488.402(f)(1), in addition to the reasons already cited, we believe that engaging in proposed rulemaking would be unnecessary. In the case of this modification of our enforcement process, no change in the regulation text is needed since it is only an interpretation of the current rule that is being affected. Beyond this, providers will receive no less notice of impending adverse actions than they have in the past. The only difference will be that the letter they receive will arrive under the signature of a State official rather than one from a HCFA regional office. We believe this change will permit HCFA and the States to focus more swiftly on specific instances of noncompliance and, therefore, it is in the public interest for this change to be accomplished as quickly as possible.

Therefore, we find good cause to waive the notice of proposed rulemaking and to issue this rule as a final rule with comment. We are, however, providing a 60-day comment period and will respond to comments we receive in any subsequent Federal Register document.

VI. Collection of Information Requirements

Sections 4204(b) and 4214(d) of the Omnibus Budget Reconciliation Act of 1987 (Public Law 100-203) provide a waiver of Office of Management and Budget review of information collection requirements for the purpose of implementing the nursing home reform amendments and these enforcement provisions as referred to in section 4203 of that act.

VII. Regulatory Impact Statement

We have examined the impacts of this final rule with comment as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Public Law 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA small entities include small businesses, non-profit organizations and government agencies. For purposes of the RFA, most long term care facilities are considered to be small entities.

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a *13359 significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA.

The intent of the "per instance" penalty in this final rule and the "limited per day" option discussed earlier in this preamble is to offer greater administrative ease to the survey agency in applying penalties and offer a more flexible approach to ensuring compliance. The current per day penalty is administratively difficult to apply, consuming increased surveyor time. The "per instance" and "limited per day" would allow the imposition of financial penalties that on a per case basis may be less onerous. In developing these two options HCFA is recognizing the range

of severity of violations and providing survey agencies increased enforcement flexibility, in the form of additional civil money penalty options.

We view the anticipated results of this rule as beneficial to nursing home residents. Specifically, we believe that a per instance civil money penalty will allow us to more specifically tailor the response to facility noncompliance in a way that assures that appropriate resident care occurs. Nevertheless, we recognize that this rule could be controversial and may be responded to unfavorably by some interested parties. We also recognize that not all of the potential effects of this rule can be definitely anticipated, especially in view of their interaction with other Federal, State, and local activities regarding health and safety assurance. In particular, considering the effects of our simultaneous efforts to improve the survey and enforcement activities, through both new and existing instruments and the nursing home provider's responsibility to maintain continuous compliance with the participation requirements, it is impossible to quantify meaningfully the future effect of this rule on facilities' compliance activities or costs. We also are unable to project the frequency with, or increase or decrease in, which facilities will be found to be out of compliance and subject to the imposition of a civil money penalty. While it is not possible to anticipate frequency HCFA must consider the facility's financial condition in determining the amount of penalty if a civil money penalty is selected.

Affected Entities

As of August 24, 1998, there are a total of 17,346 nursing homes participating in the Medicare and Medicaid programs; there are 1,488 skilled nursing facilities certified for Medicare, 2,343 nursing facilities certified for Medicaid, and 13,515 dually participating facilities certified for both Medicare and Medicaid. The majority (65 percent) of these facilities are proprietary. Approximately 28 percent are not-for-profit and 7 percent are government operated.

In order to determine what is a small entity, we use \$5 million as a threshold. In estimating the number of nursing facilities with annual revenues in excess of \$5 million, bed size was used as a proxy. We assumed facilities with 120 beds or more would have annual gross revenues of \$5 million or more. Information on average revenue per day was obtained from the HCFA Office of the Actuary, National Health Statistics Group. In determining the facility bed size, the national 1997 average facility occupancy was considered. The occupancy rate was taken from a January 1999 report "Nursing Facilities, Staffing, Residents, and Facility Deficiencies, 1991 Through 1997." The Online Survey Certification and Report (OSCAR) was used in preparing the report as well as our using the data to gather information regarding facility size. Approximately 61 percent of the proprietary facilities have 119 beds or fewer. Government-owned facilities are not considered small entities because there are not independently owned and operated even though they are not-for-profit.

There should be no additional cost to the provider. This is based upon the fact the regulations and operating directions against which compliance is evaluated have been readily available and widely distributed to the provider community for a number of years and the requirements have not changed. The requirements against which compliance is evaluated are known and the provider has both the ability and expectation to maintain compliance. The provider should be in compliance. This would mean no civil money penalty would be imposed. However, should the

provider be determined out of compliance and a decision reached to impose a per instance civil money penalty, it is difficult to project the number of times that may occur. While it may not be fully instructive to evaluate the impact of the current process for imposing a civil money penalty the only experience the HCFA has to draw upon is our experience since the regulation became effective in July 1995. Historical information spanning the three fiscal years since July 1995 indicates the average number of facilities per year that have had civil money penalties imposed is between one and 1.5 and 3 percent. The yearly average amount of the civil money penalty per facility has been \$15,672 to \$21,280. The facility's management also has the ability and legal responsibility to maintain compliance with requirements. Since the majority of the businesses have annual operating budgets in excess of \$1 million dollars, the impact of the per instance civil money penalty, when compliance is not maintained, does not appear particularly onerous.

We do not know the impact of this rule on nursing homes. As has previously been stated, if the facility is in substantial compliance with Federal regulations, there is no basis to utilize any enforcement remedy. However, should a remedy be indicated, a number of alternative remedies may be considered in addition to a civil money penalty. It would not be accurate to assume that a civil money penalty would be the remedy of choice or the one most frequently used. Selection of enforcement remedies appropriate to the noncompliance requires careful consideration on the part of the regulatory agency and does not automatically imply a civil money penalty will be more heavily utilized than the per day civil money penalty, we have no data to support that perspective.

We have also considered the potential impact of the "limited per day" methodology of imposing a civil money penalty on nursing homes. The same difficulty is present in attempting to assess the impact of this approach as is present with the per instance provision. It is not possible to project the frequency of noncompliance or increases or decreases in the number of facilities that will be found to be out of compliance and subject to imposition of a civil money penalty. This is especially true when considering that selection of a civil money penalty is not a requirement and but one of an array of remedies that may be selected.

A nursing home certified to participate in the Medicare and Medicaid programs is expected to be in compliance with Federal requirements as a condition of receiving payment for services provided to beneficiaries. If the provider is in compliance, no action to impose a remedy, which could include a civil money penalty, would be justified. However, should the provider be determined out of compliance and a decision reached to impose a civil money penalty, it is difficult to project the number of times that may occur. As we have indicated, if a civil money *13360 penalty is selected as an enforcement option, the facility's financial condition must be considered in determining the amount of the penalty.

There are currently a number of activities occurring that we believe will sharpen public and provider awareness of problems in nursing homes. These activities include the President's "Initiatives to Improve the Quality of care In Nursing Homes" and activities of the Senate Committee on Aging. We believe that the increased awareness of nursing homes problems may influence greater facility compliance and mitigate against increased use of remedies to achieve compliance with Federal requirements.

Because this rule affects no rural hospitals, we are not preparing an analysis for section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

This rule has been reviewed in accordance with the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 et seq.), which requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an annual expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million. Although this interim final rule will affect nursing facilities, we anticipate this effect to be less than \$100 million in the aggregate.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CAR Part 488

Health facilities, Medicare, Reporting and recordkeeping requirements. For the reasons set forth in the preamble, 42 CAR part 488, subpart F, is amended as set forth below:

PART 488--SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

1. The authority citation for Part 488 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart Enforcement of Compliance for Long-Term Care Facilities with Deficiencies

2. In §488.402, paragraph (f)(5) is revised to read as follows:

§488.402 General provisions.

(f) Notification requirements--***

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

3. In §488.408, the introductory text of paragraphs (d)(1), (e)(1), and (e)(2) are republished, paragraphs (d)(1)(iv) and (e)(1)(iv) are added, and paragraph (3)(2)(ii) is revised to read as follows:

§488.408 Selection of remedies.

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

(iv) Civil money penalty of \$1,000-\$10,000 per instance of noncompliance.

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

(iv) Civil money penalty of \$1,000-\$10,000 per instance of noncompliance.

(2) When there are one or more deficiencies that constitute immediate jeopardy to resident health or safety--

(ii) HCFA and the State may impose a civil money penalty of \$3,050-\$10,000 per day or \$1,000-\$10,000 per instance of noncompliance, in addition to imposing the remedies specified in paragraph (e)(2)(i) of this section.

4. Section 488.430(a) is revised to read as follows:

§488.430 Civil money penalties: Basis for imposing penalty.

(a) HCFA or the State may impose a civil money penalty for either the number of days a facility is not in substantial compliance with one or more participation requirements or for each instance that a facility is not in substantial compliance, regardless of whether or not the deficiencies constitute immediate jeopardy.

5. IN §488.432, the section heading and paragraphs (a)(2), (b), and (c) are revised to read as follows:

§488.432 Civil money penalties: When a penalty is collected.

(a) When a facility requests a hearing. ***

(2) (I) If a facility requests a hearing within the time specified in paragraph (a)(1) of this section, for a civil money penalty imposed per day, HCFA or the State initiates collection of the penalty when there is a final administrative decision that upholds HCFA's or the State's determination of noncompliance after the facility achieves substantial compliance or is terminated.

(ii) If a facility requests a hearing for a civil money penalty imposed per instance of noncompliance within the time specified in paragraph (a)(1) of this section, HCFA or the State initiates collection of the penalty when there is a final administrative decision that upholds HCFA's or the State's determination of noncompliance.

(b) When a facility does not request a hearing for a civil money penalty imposed per day. (1) If a facility does not request a hearing in accordance with paragraph (a) of this section, HCFA or the State initiates collection of the penalty when the facility--

(i) Achieves substantial compliance; or

(ii) Is terminated.

(2) When a facility does not request a hearing for a civil money penalty imposed per instance of noncompliance. If a facility does not request a hearing in accordance with paragraph (a) of this section, HCFA or the State initiates collection of the penalty when the time frame for requesting a hearing expires.

(c) When a facility waives a hearing. (1) If a facility waives, in writing, its right to a hearing as specified in §488.436, for a civil money penalty imposed per day, HCFA or the State initiates collection of the penalty when the facility--

- (i) Achieves substantial compliance; or (ii) Is terminated.
- (2) If a facility waives, in writing, its right to a hearing as specified in §488.436, for a civil money penalty imposed per instance of noncompliance, HCFA or the State initiates collection of the penalty upon receipt of the facility's notification.

- 6. In §488.434, the introductory text of paragraph (a)(2) is republished and paragraphs (a)(2)(iii), (a)(2)(v), and (a)(2)(vi) are revised to read as follows:

§488.434 Civil money penalties: Notice of penalty.

(a) HCFA notice of penalty. ***

(2) Content of notice. The notice that HCFA sends includes--

(iii) The amount of penalty per day of noncompliance or the amount of the penalty per instance of noncompliance;

(v) The date of the instance of noncompliance or the date on which the penalty begins to accrue;

(vi) When the penalty stops accruing, if applicable;

- 7. In §488.438, the introductory text of paragraph (a) is redesignated as (a)(1) and republished; paragraphs (a)(1) and (a)(2) are redesignated as paragraphs (a)(1)(i) and (a)(1)(ii), respectively; a new paragraph (a)(2) is added; and #13361 paragraphs (c) and (d) are revised to read as follows:

§488.438 Civil money penalties: Amount of penalty.

(a) Amount of penalty--(1) Per day penalties. The per day penalties are within the following ranges, set at \$50 increments:

(i) Upper range. ***

(ii) Lower range. ***

(2) Per instance penalty. When penalties are imposed for an instance of noncompliance, the penalties will be in the range of \$1,000-\$10,000 per instance.

(c) Decreased penalty amounts. Except as specified in paragraph (d)(2) of this section, if immediate jeopardy is removed, but the noncompliance continues, HCFA or the State will shift the penalty amount imposed per day to the lower range.

(d) Increased penalty amounts. (1) Before a hearing requested in accordance with §488.432(a), HCFA or the State may propose to increase the per day penalty amount for facility noncompliance which, after imposition of a lower level penalty amount, becomes sufficiently serious to pose immediate jeopardy.

(2) HCFA does and the State must increase the per day penalty amount for any repeated deficiencies for which a lower level penalty amount was previously imposed, regardless of whether the increased penalty amount would exceed the range otherwise reserved for nonimmediate jeopardy deficiencies.

8. In §488.440, paragraphs (a), (c), (d), (g), and (h); the introductory text of paragraphs (b) and (e); and paragraph (f)(1) are revised to read as follows:

§488.440 Civil money penalties: Effective date and duration of penalty.

- (a) (1) The per day civil money penalty may start accruing as early as the date that the facility was first out of compliance, as determined by HCFA or the State.
- (2) A civil money penalty for each instance of noncompliance is imposed in a specific amount for that particular deficiency.
- (b) The per day civil money penalty is computed and collectible, as specified in §§488.432 and 488.442, for the number of days of noncompliance until the date the facility achieves substantial compliance, or, if applicable, the date of termination when--

- (c) The entire penalty, whether imposed on a per day or per instance basis, is due and collectible as specified in the notice sent to the provider under paragraphs (d) and (e) of this section.
- (d) (1) When a civil money penalty is imposed on a per day basis and the facility achieves substantial compliance, HCFA does or the State must send a separate notice to the facility containing the following information:
- (i) The amount of penalty per day.
- (ii) The number of days involved.
- (iii) The total amount due.
- (iv) The due date of the penalty.
- (v) The rate of interest assessed on the unpaid balance beginning on the due date, as provided in §488.442.
- (2) When a civil money penalty is imposed for an instance of noncompliance, HCFA does or the State must send a separate notice to the facility containing the following information:
- (i) The amount of the penalty.
- (ii) The total amount due.
- (iii) The due date of the penalty.
- (iv) The rate of interest assessed on the unpaid balance beginning on the due date, as provided in §488.442.
- (e) In the case of a facility for which the provider agreement has been terminated and on which a civil money penalty was imposed on a per day basis, HCFA does or the State must send this penalty information after the--

- (f) (1) In the case of noncompliance that does not pose immediate jeopardy, the daily accrual of per day civil money penalties is imposed for the days of noncompliance prior to the notice specified in §488.434 and an additional period of no longer than 6 months following the last day of the survey.

- (g) (1) IN a case when per day civil money penalties are imposed, when a facility has deficiencies that pose immediate jeopardy, HCFA does or the State must terminate the provider agreement within 23 calendar days after the last day of the survey if the immediate jeopardy remains.
- (2) The accrual of the civil money penalty imposed on a per day basis stops on the day the

provider agreement is terminated.

- (h) (1) If an on-site revisit is necessary to confirm substantial compliance and the provider can supply documentation acceptable to HCFA or the State agency that substantial compliance was achieved on a date preceding the revisit, penalties imposed on a per day basis only accrue until that date of correction for which there is written credible evidence.
 - (2) If an on-site revisit is not necessary to confirm substantial compliance, penalties imposed on a per day basis only accrue until the date of correction for which HCFA or the State receives and accepts written credible evidence.
9. In §488.442, the heading of paragraph (a) is revised, paragraphs (b) through (f) are redesignated as paragraphs (c) through (g), respectively, and new paragraph (b) is added to read as follows:

+488.442 Civil money penalties: Due date for payment of penalty.

(a) When payments are due for a civil money penalty imposed on a per day basis--

(b) are due for a civil money penalty imposed for an instance of noncompliance. Payment of a civil money penalty is due 15 days after one of the following dates:

- (1) The final administrative decision is made;
- (2) The time for requesting a hearing has expired and the facility did not request a hearing; or
- (3) The facility waived its right to a hearing.

10. In §488.454, the introductory text of paragraph (a) is revised, paragraph (d) is redesignated as paragraph (e) and revised, and new paragraph (d) is added to read as follows:

§488.454 Duration of remedies.

(a) Except as specified in paragraphs (b) and (d) of this section, alternative remedies continue until--

(d) In the case of a civil money penalty imposed for an instance of noncompliance, the remedy is the specific amount of the civil money penalty imposed for the particular deficiency.

(e) If the facility can supply documentation acceptable to HCFA or the State survey agency that it was in substantial compliance, if necessary, on a date preceding that of the revisit, the remedies terminate on the date that HCFA or the State can verify as the date that substantial compliance was achieved and the facility demonstrated that it could maintain substantial compliance, if necessary.

(Catalog of Federal Domestic Assistant Program No. 93.778, Medical Assistance Program; Program No. 93.773, Medicare--Hospital Insurance; and Program No. 93.774, Medicare--Supplementary Medical Insurance Program)

#13362 Dated: February 12, 1999.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Dated: March 3, 1999.

Donna E. Shalala, Secretary

[FR Doc. 99-6618 Filed 3-16-99; 9:20 am]

BILLING CODE 4120-01-P

64 FR 13354-01, 19999 WL 143479 (F.R.)

END OF DOCUMENT