Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

42 CFR Part 488

[CMS–2435–P]

Medicare and Medicaid Programs; Civil Money Penalties for Nursing Homes

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise and expand current Medicare and Medicaid regulations regarding the imposition and collection of civil money penalties by CMS when nursing homes are not in compliance with Federal participation requirements in accordance with the Patient Protection and Affordable Care Act of 2010.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. EST on August 11, 2010.

ADDRESSES: In commenting, please refer to file code CMS–2435–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the "More Search Options" tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2435–P, P.O. Box 8012, Baltimore, MD 21244–8012.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2435–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Lori Chapman, (410) 786–9254.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments. Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

To participate in the Medicare program or the Medicaid program, or both, long-term care facilities must be certified as meeting Federal participation requirements. Long-term care facilities include skilled nursing facilities (SNFs) for Medicare and nursing facilities (NFs) for Medicaid. The Federal participation requirements for these facilities, generally referred to as "nursing home(s)," "facility" or "facilities" in this proposed rule, are specified in regulations at 42 CFR part 483, subpart B.

Section 1864(a) of the Social Security Act (the Act) authorizes the Secretary to enter into agreements with State survey agencies to determine whether 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 Medicare and Medicaid related surveys are used by CMS and the State Medicaid agency, respectively, as the basis for a decision to enter into or deny a provider agreement, recertify facility participation in one or both programs, or terminate the facility from the program. They are also used to determine whether one or more enforcement remedies should be imposed where noncompliance with Federal requirements 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 statutory enforcement remedies available to the Secretary and the States to address facility noncompliance are civil money penalties. Authorized by sections 1819(h) and 1919(h) of the Act, civil money penalties may be imposed for each day or each instance of facility noncompliance, as well as for past instances of noncompliance even if a facility is in compliance at the time of the current survey. The regulations that govern the imposition of civil money penalties, as well as other enforcement remedies authorized by the statute, were published in the **Federal Register** on November 10, 1994 (59 FR 56116),and on March 18, 1999 (64 FR 13354). These rules are set forth at 42 CFR Part 488, Subpart F, and the provisions directly affecting civil money penalties are set forth at § 488.430 through § 488.444.

A per day civil money penalty may be imposed from $50 up to $10,000 for each day of noncompliance. An upper civil money penalty range of $3,050 up to $10,000 per day may be imposed for noncompliance that constitutes immediate jeopardy, meaning the noncompliance has caused or is likely to cause serious injury, harm, impairment or death to a resident, and as specified in § 488.438(d)(2) for repeat deficiencies. A lower range of $50 up to $3,000 per day may be imposed for noncompliance that does not constitute immediate jeopardy. The current regulations at § 488.438(a)(2) also specify that a civil money penalty may be imposed per instance of facility noncompliance in the range of $1,000 to $10,000 per instance. Current regulations at § 488.438(f)(2) also provide that, among other factors, a facility's financial condition will be considered when determining the amount of a civil money penalty.

Facilities that are dissatisfied with a certification of noncompliance have an informal opportunity, if they request it, to dispute cited deficiencies upon receipt of the official statement of deficiencies. For surveys conducted pursuant to section 1864 of the Act, this informal dispute resolution process is provided by the State. The requirement for informal dispute resolution is currently specified at § 488.331. Policy guidance in section 7212C of CMS's *State Operations Manual* (Pub. L. 100–07) specifies the mandatory elements that must be included in each State's informal dispute resolution process. While States have the option to involve outside persons or entities that they believe to be qualified to participate in the informal dispute resolution process, it is the States, not the outside individuals or entities that are responsible and accountable for the informal dispute resolution decisions. Further, when a facility is successful during the informal dispute resolution process at demonstrating that deficiencies should not have been cited, and CMS accepts these informal dispute resolution findings, the deficiency is or deficiencies are removed from the Statement of Deficiencies. Any enforcement sanctions, not only a civil money penalty, that were imposed as a result of those removed deficiencies are rescinded and adjusted accordingly.

When civil money penalties are imposed by the State and CMS for a determination of noncompliance with nursing home participation requirements and the facility requests a hearing on that determination, a civil money penalty is not currently due and collectible under § 488.432 until after the facility has had an opportunity for an administrative hearing and received a final agency decision about the noncompliance upon which the penalty was imposed. Only with respect to civil money penalties does the Act specify that a nursing home provider would be entitled to a hearing before an adverse action is taken against it. Aside from this one exception for civil money penalties, as provided in section 1128A of the Act, appeal procedures for both the Medicare and Medicaid programs provide the opportunity for formal relief only after enforcement sanctions have taken effect. Indeed, sections 1819(h)(5) and 1919(h)(8) of the Act specifically state that the remedies permitted under the statute may be imposed during the pending of any hearing. This is consistent with the intent of the enforcement provisions which is to impose remedies as soon as possible in order to protect the residents.

Regulations at § 488.436 provide that a facility may waive its right to a hearing within specified timeframes and procedures and, as a result, will have the civil money penalty reduced by 35 percent. This reduction is intended to encourage facilities to carefully consider their position in terms of substantial compliance, as well as the costs they will incur in litigating the matter, before engaging the hearing process. Reducing a civil money penalty by 35 percent is based on the recognition that a legal challenge is costly to both the provider and to CMS.

Current regulations at § 488.432 specify when the civil money penalty is collected, based on whether or not a hearing is requested:

- When a facility appropriately requests a hearing, in accordance with specified procedures, on the determination of noncompliance that is the basis for a per day civil money penalty, the penalty is collected when there is a final administrative decision that upholds the State's or CMS's determination after the facility achieves substantial compliance or is terminated.
- When a facility does not request a hearing, in accordance with specified procedures, on the determination of noncompliance that is the basis for a per day civil money penalty, the penalty is collected when the facility achieves substantial compliance or is terminated.
- When a facility waives its right to a hearing, in accordance with specified procedures, on the determination of noncompliance that is the basis for a per day civil money penalty, the penalty is collected when the facility achieves substantial compliance or is terminated.
- When a facility appropriately requests a hearing, in accordance with specified procedures, on the determination of noncompliance that is the basis for a per instance civil money penalty, the penalty is collected when there is a final administrative decision that upholds the State's or CMS's determination of noncompliance.
- When a facility does not request a hearing, in accordance with specified procedures, on the determination of noncompliance that is the basis for a per instance civil money penalty, the penalty is collected when the time frame for requesting a hearing expires.
- When a facility waives its right to a hearing, in accordance with specified procedures, on the noncompliance that is the basis for a per instance civil money penalty, the penalty is collected upon receipt of the facility's notification.

As specified in section 1128A(f) of the Act, which is incorporated in sections 1819(h) and 1919(h) of the Act, and consistent with the way other civil money penalties are recovered, monies collected by CMS are returned to the State in proportion commensurate with the relative proportion of Medicare and Medicaid beds at the facility in use by residents of the respective programs on the date the civil money penalty begins to accrue, and remaining funds are deposited as miscellaneous receipts of the United States Department of the Treasury. Section 1919(h)(2)(A)(ii) of the Act specifies that civil money penalties collected by the State must be applied to the protection of the health or property of residents of any nursing facility that the State or CMS finds deficient, including payment for the cost of relocating residents to other facilities, maintenance of operation of a facility pending correction of deficiencies or closure, and

reimbursement of residents for personal funds lost.

II. Provisions of the Proposed Regulations

Section 6111 of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), enacted on March 23, 2010, amended sections 1819(h) and 1919(h) of the Act to incorporate specific provisions pertaining to the imposition and collection of civil money penalties when facilities do not meet Medicare and Medicaid participation requirements.

We believe that through these new statutory provisions, Congress has expressed its intent to improve efficiency and effectiveness of the nursing home enforcement process, particularly as it relates to civil money penalties imposed by CMS.

Section 6111 of the Affordable Care Act provides the Secretary discretion to reduce the amount of a civil money penalty by not more than 50 percent in cases where a facility self-reports and promptly corrects a deficiency for which a penalty was imposed within ten calendar days of the date of imposition. However, the Secretary may not reduce the civil money penalty if either of the following is true: (1) The Secretary has reduced a civil money penalty imposed in the preceding year under this provision with respect to a repeat deficiency; or (2) the penalty is imposed on the facility for a deficiency that is found to result in a pattern of harm or widespread harm, immediately jeopardizes the health or safety of a resident or residents, or results in the death of a resident of the facility. Section 6111 of the Affordable Care Act also requires the Secretary to issue regulations that provide facilities an opportunity to participate in an independent informal dispute resolution process prior to the collection of a civil money penalty, allows for the collection and deposit of a civil money penalty in an escrow account prior to the resolution of any formal appeals, provides for return of escrowed civil money penalty funds in cases where a nursing home is successful in a formal appeal, and allows for a portion of the retained penalty funds pertinent to Medicare to support activities that benefit residents.

These provisions in section 6111 of the Affordable Care Act seek to reduce the delay which results between the identification of problems with noncompliance and the effect of certain penalties that are intended to motivate a nursing home to maintain continuous compliance with basic expectations regarding the provision of quality care and eliminate a facility's ability to significantly defer the direct financial effect of an applicable civil monetary penalty until after an often long litigation process.

To implement these new statutory provisions, we are proposing to revise 42 CFR part 488 by adding new § 488.431 and § 488.433. We are also proposing revisions to existing regulations throughout part 488 to further incorporate the new statutory provisions. These proposed changes would be consistent with Section 6111 of the Affordable Care Act. Specifically, this proposed rule would allow for civil money penalty reductions when facilities self-report and promptly correct their noncompliance; offer in cases where civil money penalties are imposed an independent informal dispute resolution process where interests of both facilities and residents are represented and balanced; provide for the establishment of an escrow account where civil money penalties may be placed until any applicable administrative appeal processes have been completed; and, improve the extent to which civil money penalties collected from Medicare facilities can benefit nursing home residents. Through the proposed revisions, we intend to directly promote and improve the health, safety, and overall well-being of residents.

A. Proposed Establishment of an Escrow Account for Civil Money Penalties

Under the existing process, facilities are able to avoid paying a civil money penalty for years because it can often take a long time for administrative appeals to be completed. Concerns about the delays in payment of a civil money penalty have been raised in independent reports issued by both the United States Government Accountability Office (GAO) and the Office of the Inspector General of the Department of Health and Human Services (OIG). These referenced reports are identified as GAO–07–241, "Efforts to Strengthen Federal Enforcement Have Not Deterred Some Homes from Repeatedly Harming Residents," (March 2007), and OEI–06–02–00720, "Nursing Home Enforcement: The Use of Civil Money Penalties," (April 2005). Both GAO and OIG studied the civil money penalty collection process for nursing homes. Each concluded that the significant time that can elapse between identification of noncompliance and the facility's payment of an imposed civil money penalty diminishes the immediacy of the enforcement response, insulates the facility from the repercussions of enforcement, and may undermine the sanction's deterrent effect. For example, the OIG reported that, in the cases they reviewed, collection of civil money penalties in appealed cases took an average of 420 days. As a result of its own independent study, GAO recommended that CMS seek a legislative change that would allow for the collection of civil money penalties before exhaustion of appeals.

Sections 6111(a) and (b) of the Affordable Care Act created new authorities at sections 1819(h) and 1919(h) of the Act that now permit the Secretary to collect and place civil money penalties into an escrow account pending the resolution of any formal appeal. We believe that through the passage of this specific provision and the creation of an exception to current collection timeframe for civil money penalties imposed by CMS, the Congress expressed its intent to address the current delay in collection of civil money penalties and mitigate the deleterious effect of such delays that the GAO and OIG identified in their reports.

Specifically, sections 6111(a) and (b) of the Affordable Care Act expand sections 1819(h)(2)(B)(ii) and 1919(h)(3)(C)(ii) of the Act by adding a new subsection (IV)(bb) which states that, in the case of per day civil money penalties, the penalty will not be imposed until after a facility has had an opportunity for an independent informal dispute resolution process by which the facility may informally challenge the noncompliance on which the penalty was based. (The added provisions regarding the new independent informal dispute resolution process are discussed later in section II–C. of this preamble.)

In the proposed rule, we interpret the language of this new section (IV)(bb) to mean that any per day civil money penalty would be effective and continue to accrue but would not be collected during the time that the determination of noncompliance which led to the imposition of a civil money penalty is subject to the independent informal dispute resolution process. This is consistent with other provisions of Section 6111 of the Affordable Care Act and when viewed in the context of the purpose of the enforcement process of the Social Security Act. First, new subsection (IV)(cc) of sections 1819(h)(2)(B)(ii) and 1919(h)(3)(C)(ii), as amended by section 6111 of the Affordable Care Act, provide for the collection of the civil money penalty upon completion of an independent informal dispute resolution process. If the per day civil money penalty did not apply and accrue during the period of

an independent informal dispute resolution process, there would not be any civil money penalty funds to collect upon completion of the process in those cases where the dispute resolution does not result in any change to the findings. In those cases where this independent informal dispute resolution process does result in a change to the findings that would lower the civil money penalty amounts, then the accrual would be immaterial because the civil money penalties were reduced or rescinded back to the effective date of the civil money penalty. Second, it has been CMS' longstanding position that sections 1819(h) and 1919(h) of the Act provide that a per day civil money penalty can begin to accrue as early as the date that a facility was first determined to be out of compliance and continues to accrue, without interruption, until a facility has achieved substantial compliance or is terminated from the program. Additionally, the Act also provides that the effective date of a civil money penalty can be retroactive to the date of an adverse event that was documented through the survey process to have occurred prior to the issuance of a formal written notice informing the facility that a per day civil money penalty has been applied. Section 6111 of the Affordable Care Act does not change the existing nursing home enforcement process; rather it adds an additional process to be available to facilities as a result of the Secretary's new authority to collect a civil money penalty before exhaustion of administrative remedies. Third, since a facility may continue to be out of substantial compliance for a period of time until it is terminated from the program, an interruption in the civil money penalty accrual would be contrary to the intended effect of creating financial incentives for facilities to maintain compliance and promptly correct any noncompliance. Since we believe Congress intended to speed and strengthen the motivational and deterrent effects of civil money penalties, we believe that suspending the accrual of a civil money penalty while the underlying noncompliance was being informally challenged would undermine such motivational effects.

We therefore propose that CMS will not collect applicable civil money penalty funds until either an independent informal dispute resolution process is completed or 90 days has passed since the notice of civil money penalty imposition has been issued, whichever is earlier. The 90 day period is the maximum combined time period permitted from the date of the notice of civil money penalty imposition (when a facility has the opportunity to request an independent informal dispute resolution) to the date for completion of the independent informal dispute resolution process itself. This combined maximum time period is consistent with the provisions of new sections 1819(h)(2)(B)(ii)(IV)(cc) and 1919(h)(3)(C)(ii)(IV)(cc) of the Act, as amended by section 6111 of the Affordable Care Act (which is discussed in more detail below).

1. Collection and Placement in Escrow Account

Sections 6111(a) and (b) of the Affordable Care Act add new sections 1819(h)(2)(B)(ii)(IV)(cc) and 1919(h)(3)(C)(ii)(IV)(cc) of the Act which provide the authority for CMS to collect and place into escrow accounts civil money penalties. This may be done on the earlier of (1) the date when a requested independent informal dispute resolution process is completed, or (2) 90 days after imposition of the civil money penalty. We are proposing to implement these requirements at § 488.431(b)(1)(i) and § 488.431(b)(1)(ii). While the amended statutory language contemplates that a facility will be either wholly successful or unsuccessful in challenging its determination of noncompliance during the independent informal dispute resolution process, the proposed regulation reflects an understanding that there are times when a facility is partly successful. In such instances, the facility may be able to argue successfully for change to only some of its cited noncompliance. If such change as a result of the independent informal dispute resolution were to affect the civil money penalty amounts owed, (for example, through deletion of a germane deficiency), then the amount initially imposed would need to be adjusted accordingly before being collected and placed in the escrow account.

2. When a Facility Is Successful in a Formal Administrative Appeal

Sections 6111(a) and (b) of the Affordable Care Act amend sections 1819(h)(2)(B)(ii) and 1919(h)(3)(C)(ii) of the Act by adding new section (IV)(dd) which provides that collected civil money penalties will be kept in an escrow account pending the resolution of any subsequent formal appeals (as distinct from an informal dispute resolution process). Sections 6111(a) and (b) of the Affordable Care Act also adds new section (IV)(ee) to revise sections 1819(h)(2)(B)(ii) and 1919(h)(3)(C)(ii) of the Act, to require that when a final administrative decision results in the successful appeal of a facility's cited determination of noncompliance that led to the imposition of the civil money penalty, that civil money penalty amount being held in escrow will then be returned to the facility, with interest. We are proposing at § 488.431(d)(2) that if the administrative law judge (ALJ) reverses the civil money penalty determination in whole or in part, the escrowed amount continues to be held pending expiration of the time for CMS to appeal the ALJ decision or, where CMS does appeal, a Departmental Appeals Board decision affirming the ALJ's reversal of the civil money penalty. We are proposing to implement these new requirements at proposed § 488.431(d). We believe these new statutory provisions contemplate not only an absolute situation where the facility is either wholly successful or unsuccessful in its administrative appeal of a determination which led to a civil money penalty imposition, but that they also include situations in which a facility is only partially successful in its appeal. Thus, the proposed regulation recognizes this possibility and provides that CMS will return collected civil money penalty amounts commensurate with the final administrative appeal results.

We do not plan to include specifics in this proposed rule about how these requirements would be operationalized because we believe that such guidance is more appropriately suited for inclusion in our *State Operations Manual* after collaboration with interested stakeholders. However, we do expect that the collection of a per day civil money penalty under this proposed rule may be a two-step process. In proposed § 488.431(b)(2),we expect that in instances when a facility has not achieved substantial compliance at the time a per day civil money penalty can be collected and placed in an escrow account, that collection would consist of the penalty amount that has accrued from the effective date of the penalty through the date of collection. Another collection would need to occur later in the process for any final balance determined to be due and payable once the facility achieves substantial compliance or is terminated from the program.

B. Proposed Reduction of a Civil Money Penalty by 50 Percent for Self-Reporting and Prompt Correction of Noncompliance

Sections 6111(a) and (b) of the Affordable Care Act add new sections 1819(h)(2)(B)(ii)(II)and (III) and

1919(h)(3)(C)(ii)(II) and (III) of the Act. These sections establish new authorities for CMS to reduce a civil money penalty it imposes by up to 50 percent when CMS determines that a facility has self-reported and promptly corrected its noncompliance. This new provision explicitly provides that such reduction is not applicable for noncompliance that constitutes immediate jeopardy to resident health and safety, or that constitutes either a pattern of harm or widespread harm to facility residents, or that resulted in a resident's death. Additionally, the new provisions clearly specify that this reduction does not apply to a civil money penalty that was imposed for a repeated deficiency that resulted in a civil money penalty reduction under this section in the previous year.

This proposed rule would permit CMS to reduce a civil money penalty if a facility self-reports and promptly corrects quality problems. The new reduction authority works in harmony with section 6102 of the Affordable Care Act that requires nursing homes to implement an effective ethics and compliance program as well as an internal quality assurance and performance improvement program. The requirements in both sections 6111 and 6102 of the Affordable Care Act emphasize the value of systems within a nursing home that can continuously stream performance information back to its facility management with the expectation that problems with the provision of quality care would be identified and promptly remedied, and that system improvements would be put in place to prevent recurrence. New sections 1819(h)(2)(B)(ii)(II) and (III) and 1919(h)(3)(C)(ii)(II) and (III) of the Act, as amended by sections 6111(a) and (b) of the Affordable Care Act, support section 6102 of the Affordable Care Act, promoting quality assurance and improvement by adding a financial incentive through the 50 percent reduction of a civil money penalty following self-reporting and prompt correction of such problems. We are proposing to implement these new requirements at § 488.438(c).

The language of the new statutory provision permissively states that the Secretary may reduce an imposed civil money penalty by up to 50 percent "where a facility self-reports and promptly corrects a deficiency for which a penalty was imposed under this clause not later than 10 calendar days after the date of such imposition." We propose that the 50 percent reduction would be applied only where a number of conditions are met. First, the facility must have self-reported the noncompliance to CMS or the State before it was identified by CMS or the State and before it was reported to CMS or the State by means of a complaint lodged by a person other than an official representative of the nursing home. Second, correction of the noncompliance must have occurred within ten calendar days of the date that the facility identified the deficient practice. For a number of reasons stated below, we propose not to permit a 50 percent reduction when the self-reporting or the correction occurred at any later point in time. To credit a facility with "self-reporting" only after a facility has been surveyed and noncompliance has been discovered by CMS would not meet the common sense meaning of "self-reporting." We have proposed to give meaning to this provision in a manner that can best encourage facilities to self-report their noncompliance so that they can take the necessary corrective action as quickly as possible, without waiting for the State or CMS to identify or to cite the noncompliance, and thus be rewarded for their efforts. Therefore, under the discretion provided to us in this provision, we are declining to reduce a civil money penalty by 50 percent when a facility attempts to self-report noncompliance after it has already been identified by CMS. Rather, we propose at § 488.438(c)(2)(i) and (ii) that, among other criteria, in order for a facility to receive this 50 percent reduction, CMS must determine that the facility self-reported and corrected the noncompliance within 10 days of identifying it, and before it was identified by CMS or the State. In addition we specify that any attempted self-reporting of noncompliance by a facility that occurs after it was already identified by CMS will not be considered for any reduction under this proposed provision.

In accordance with sections 6111(a) and (b) of the Affordable Care Act, which adds new subsections (III)(bb) to sections 1819(h)(2)(B)(ii) and 1919(h)(3)(C)(ii) of the Act, noncompliance constituting immediate jeopardy, a pattern of harm, widespread harm, or resulting in a resident's death is not eligible for the civil money penalty reduction that might otherwise be available in the case of self-reporting and prompt correction. Therefore, we are proposing to add this limitation at § 488.438(c)(2)(iv). Noncompliance at these scope and severity levels indicates a significant breakdown in facility performance and systems to the extent that, even if self-reported, warrants an equally significant consequence without the benefit of a considerable reduction. Furthermore, new sections 1819(h)(2)(B)(ii)(III)(aa) and 1919(h)(3)(C)(ii)(III)(aa) of the Act, as amended by sections 6111(a) and (b) of the Affordable Care Act, also specify that the reduction under these provisions would not apply for facilities that have repeated noncompliance for which a penalty reduction under this provision was received during the previous year. We are proposing to add this limitation at § 488.438(c)(2)(v). We believe, and Congress clearly indicated, that facilities unwilling or unable to maintain and sustain compliance with the same participation requirements over this period of time should not be rewarded with a reduced civil money penalty. This is consistent with current regulations at § 488.438(d)(2) which require that the State and CMS must increase the civil money penalty amount for any repeated deficiencies for which a lower level penalty amount was previously imposed. Current regulations at § 488.438(d)(3) define repeat deficiencies as "deficiencies in the same regulatory grouping of requirements found at the last survey, subsequently corrected, and found again at the next survey."

We are also proposing at § 488.438(c)(2)(iii) to specify that a facility must waive its right to a hearing in order to receive this 50 percent reduction. This is because, by the facility's own admission through its self-reporting and correction, it has acknowledged its noncompliance, thereby substantially eliminating the basis for any formal appeal. Should a facility elect to expend its resources on an administrative appeal, we believe it should choose between the 50 percent reduction otherwise available or pursuing the appeal. We also reinforce the incentive of a facility to invest in its program improvement by making it clear that the civil money penalty reduction for self-reporting and prompt correction will be at the maximum 50 percent level rather than any other permissible lower percentage amount.

The Secretary's authority for such a civil money penalty reduction under Section 6111 of the Affordable Care Act is discretionary and states that the reduction may be "up to 50 percent." To maximize the incentives for quality improvement, and to remove uncertainty for nursing homes, we propose in this regulation to set the percentage reduction at the highest permissible level of 50 percent in these circumstances.

In proposed § 488.436(b)(1) and § 488.438(c)(3), we are proposing to amend these sections to specify that a

facility may receive only one and not both of the available civil money penalty reductions. Under existing regulations at § 488.436(b), a facility may receive a 35 percent reduction in its civil money penalty liability if it timely waives its right to appeal the determination of noncompliance that led to the imposition of the penalty. No other criterion needs to be met in order for a facility to get this 35 percent reduction. However, in order to receive the higher 50 percent reduction in penalty, a facility must not only waive its right to a hearing, but it must also meet the specific criteria at proposed § 488.438(c)(2). A qualifying facility may receive either the 35 percent reduction for waiving its right to a hearing or the 50 percent reduction for self-reporting and promptly correcting, but in no case will the facility receive both reductions at the same time.

C. Proposed Opportunity for an Independent Informal Dispute Resolution Process

Sections 6111(a) and (b) of the Affordable Care Act adds new section (IV)(aa) to sections 1819(h)(2)(B)(ii) and 1919(h)(3)(C)(ii) of the Act, which provides a facility with the opportunity to participate in an independent informal dispute resolution process if civil money penalties have been imposed against the facility. This process is to be offered to a facility not later than 30 days after the imposition of the civil money penalty and must generate a written record prior to the collection of the penalty. Additionally, the independent informal dispute resolution process is not automatic but, consistent with the existing informal dispute resolution process under § 488.331, is available only upon the facility's request.

Language included in the House Ways and Means Committee Report H.R. 3200, while not enacted, is similar to the language used in the Affordable Care Act and offers some insight into what prompted the inclusion of this new independent review process and what was envisioned as "independent." The language in H.R. 3200 provided that any such process "shall allow independent informal dispute resolution to be conducted by an independent State agency (including an umbrella agency, such as the Health and Human Services Commission), a Quality Improvement Organization, or the state survey agency, so long as the participants in independent informal dispute resolution are not involved in the initial decision to cite the deficiency (ies) and impose the remedy (ies). Whoever is authorized to conduct independent informal dispute must not have any conflicts of interest * * *." We also note that during debate on the House floor on March 21, 2010, U.S. House of Representatives Energy and Commerce Committee Chairman Henry Waxman stated that over 40 percent of nursing home surveyors in four States told the Government Accountability Office (GAO) that their existing States' processes for informal dispute resolution favored nursing home operators over resident welfare. Representative Waxman further stated that the independent informal dispute resolution process "should be conducted by an independent State agency or entity with healthcare experience, or by the State survey agency, so long as no entity or individual who conducts independent informal dispute resolution has a conflict of interest," and that anyone should have the right to participate in the process.

While operational details of this independent review process are more appropriate for inclusion as guidance in our *State Operations Manual,* we are proposing specific core elements be included so that we can ensure the fairness and efficiency of the independent informal dispute resolution process. (CMS will notify the facility of the opportunity for this process as specified in proposed § 488.431.)

We are proposing at § 488.431(a) that CMS continues to retain ultimate authority for the survey findings and imposition of civil money penalties, and also provide that an independent informal dispute resolution must be requested by the facility within 30 days of notice of imposition of a civil money penalty. In an effort to ensure that the independent informal dispute resolution process is completed timely, we are proposing at § 488.431(a)(1) that it be completed within 60 days of the imposition of the civil money penalty. We are proposing at § 488.431(a)(2) that this process will generate a written record prior to the collection of any penalty. At proposed § 488.431(a)(3), we are requiring that the independent informal dispute resolution process include notification to an involved resident or a resident representative, as well as the state ombudsman, with respect to the opportunity to provide written comment.

We propose that the new independent informal dispute resolution process be an additional option for nursing homes and that nursing homes would retain the option to use the existing informal dispute resolution process under § 488.331. We believe that the current informal dispute resolution process can be expeditious and that it addresses a greater range of noncompliance issues that would affect other enforcement remedies than the new independent informal dispute resolution process is required to cover. The Affordable Care Act requires that the independent process be available only in cases of noncompliance for which a civil money penalty was imposed. Although States may elect to make the independent process applicable to a wider array of situations, continued maintenance of the existing informal dispute resolution process will ensure the availability of a system to address facility challenges of cited deficiencies regardless of whether other non-civil money penalty remedies are imposed.

We also propose at § 488.431(a)(4) that the new independent informal dispute resolution process be conducted at the requesting facility's expense, and expect that a system of user fees designed to cover expenses of this process will be put in place in each State. We ask for comments on alternative user fee systems. We believe this arrangement is advisable for a number of reasons. First, the current informal dispute resolution process will continue to be available to nursing homes at no charge. Second, without a user fee, the costs of the new process would be borne by the Medicare Trust Fund or other public sources that are already subject to serious fiduciary challenge. Third, in electing to use the new independent process, a nursing home must believe that there is added value to the new process as compared with either using the current (and still available) process that does not involve a user fee or requesting a formal appeal under § 498.40.

A few States have had long-standing independent informal dispute resolution programs. To gather information on the range of potential user fees, we examined the fee structure used by a contractor that has contracts with a number of such States. The purpose of our examination was to provide insight into how the user fee aspect of a national independent informal dispute resolution process might operate. In the most useful example we found, the fee structure is built on a base fee of $160 per deficiency. Upon this foundation certain variable costs are added so that the total fee amount can be responsive to the complexity of the case and the skill sets most useful in the dispute resolution process. For example, the involvement of nurses are based on an add-on hourly nurse rate (currently $145) and the involvement of a physician in some cases results in an add-on of a different

physician reviewer rate (currently $300/hour). The total fees range from $550 for a less complex case (1 to 1½ half hours of review); $800–$1,000 for a more complicated case (2–3 hours of review) and $1,000–$3,000 (3–4 hours) for the most complex cases involving immediate jeopardy or substandard quality of care. The complexity of the case is based on both the number of deficiencies that are in dispute and the amount of time it takes the nurse or physician reviewer to assess an individual deficiency. Generally, a lower scope and severity deficiency (no actual harm deficiencies) would require less review time whereas more significant deficiencies (such as immediate jeopardy or substandard quality of care) would require more time to review. The fees apply to a record review and typically do not include any telephonic or in-person conferences.

In electing to use the new process, a nursing home is free to make a marketplace decision as to whether the user fee will be worth the cost compared to the option of using the current informal dispute resolution process that involves no user fee for the facility. In electing to use the new process, we expect that the nursing home will generally consider the user fee to be less costly than filing a formal appeal. Those lesser costs may derive from both lower preparation, legal, and filing fees, together with the 35 percent reduction in the civil monetary penalty that is available under § 488.436 in situations where a nursing home elects not to request a formal hearing. We invite comments on the user fee and whether there should be distinctions made in the user fees depending on certain factors, such as whether CMS or the State changed the scope, severity, or quantity of deficiency citations as a result of information obtained through the independent informal dispute resolution process. We are also soliciting comments on whether the fee should be returned to the facility in the event that the applicable civil money penalty is completely eliminated as proposed in § 488.431(a)(4). We propose that the system of fees must be approved by CMS, be based on expected average costs, and must be uniformly applied within the State.

Finally, in view of the insights and underlying intent of this new process, as provided by the House language that is similar to the language passed in the Affordable Care Act and statements expressed by Chairman Waxman noted above, we are proposing at § 488.431(a)(5) that independent informal dispute resolution be conducted by the State under section 1864 of the Act, or an entity approved by the State and CMS, or by CMS in the case of surveys conducted only by Federal surveyors, with no conflicts of interest, such as: (i) A component of an umbrella State agency provided that the component is organizationally separate from the state survey agency; (ii) an independent entity with healthcare experience selected by the State and approved by CMS; or (iii) a distinct part of the State survey agency, so long as the entity or individual(s) conducting the independent informal dispute resolution has no conflict of interest and has not had any part in the survey findings under dispute.

D. Proposed Acceptable Uses of Civil Money Penalties Collected by CMS

Section 6111 of the Affordable Care Act establishes new acceptable uses of civil money penalties collected by CMS. Some of these collected civil money penalty funds must be applied directly to promote quality care and the well-being of nursing home residents. Additionally, the Affordable Care Act makes it clear that the specified use of such funds, collected from SNFs, SNF/NFs and NF-only facilities as a result of civil money penalties imposed by CMS, must be approved by CMS.

The Affordable Care Act provides flexibility about how civil money penalty funds collected by CMS can be used. These new provisions are also consistent with section 1919(h)(2)(A)(ii) of the Act regarding how civil money penalties may be used when collected by the State. Section 1919(h)(2)(A)(ii) of the Act provides that civil money penalties that are imposed by the State shall be applied to the protection of the health or property of nursing facility residents. the whether an acceptable use of collected fees would be to offset a portion of the cost of the independent informal dispute resolution process. The provisions of section 1128A of the Act continue to be applied to civil money penalties under sections 1819(h) and 1919(h) of the Act and specify that funds collected from Medicare facilities attributable to Title XVIII be deposited into the United States Treasury. However, the specific authorities provided by sections 6111(a) and (b) of the Affordable Care Act, which adds new subsections (IV)(ff) to sections 1819(h)(2)(B)(ii) and 1919(h)(3)(C)(ii) of the Act, expressly provide that now "a portion" of these collected funds may be used to benefit residents. Giving weight and meaning to both provisions, we are proposing that while some portion of the collected civil money penalty funds from Medicare facilities will continue to be deposited with the Treasury, another portion of those funds may be directed back into the program to be invested in activities that benefit residents. Specifically, we are proposing at § 488.433 that 50 percent of the Title XVIII portion of collected civil money penalty amounts would be used for activities that would benefit nursing home residents and that the remaining 50 percent of collected funds applicable to Title XVIII would continue to be deposited to the Department of the Treasury. This proposed division of funds reflects the focus and importance the Affordable Care Act provisions give to improving and promoting the health and well-being of nursing home residents. Furthermore, to protect against any actual or potential conflicts of interest, we specify at proposed § 488.433 that collected civil money penalty funds cannot be used for survey and certification operations and functions performed under section 1864 of the Act, but must entirely be used for activities that benefit nursing home residents and that any such activity must be approved by CMS.

With regard to distinguishing between Medicare and Medicaid proportions of civil money penalty collections for dually-participating facilities, we retain current regulations at § 488.442(f) (but amend them to include reference to proposed § 488.433) that specify the formula for determining the proportion of collected civil money penalty funds that are to be returned to the State in dually participating facilities, that is, "in proportion commensurate with the relative proportions of Medicare and Medicaid beds at the facility actually in use by residents covered by the respective programs on the date the civil money begins to accrue." These funds attributable to Title XIX are returned to the State in which the noncompliant facility that paid the civil money penalty is located, and this arrangement is continued in our proposed rule.

The Affordable Care Act provides examples of those types of activities that would be considered appropriate uses for civil money penalty monies, including—

- Assistance to support and protect residents of a facility that closes (voluntarily or involuntarily) or is decertified (including offsetting costs of relocating residents to home and community-based settings or another facility), which is found at proposed § 488.433(a) and (b);
- Projects that support resident and family councils and other consumer involvement in assuring quality care in facilities, which is found at proposed § 488.433(c);

• Facility improvement initiatives approved by CMS (including joint training of facility staff and surveyors, technical assistance for facilities implementing quality assurance programs, the appointment of temporary management firms, and other activities approved by CMS), which is found at proposed § 488.433(d).

At § 488.433(e) we propose the appointment of a temporary management firm as one possible use of collected civil money penalties, as noted in the new subsections added by section 6111 of the Affordable Care Act. Currently existing regulations at § 488.415(c) require that the temporary manager's salary is paid directly by the facility. Using civil money penalty funds to appoint a temporary management firm significantly reduces the deterrent effect of the temporary manager enforcement sanction since the costs associated with it would be paid for by collected civil money penalty funds instead of by the facility. We believe this was not the intent of Section 6111 of the Affordable Care Act. Therefore, while the proposed rule does not contemplate using civil money penalty funds for payment of the temporary manager's salary, it does contemplate using the funds for other expenses related to development and maintenance of temporary management or receivership capability (for example, recruiting, vetting, or retaining of temporary managers, or other related system infrastructure expenses). Use of funds in this manner should secure the readiness and availability of temporary manager candidates, and therefore, encourage the use of this sanction. When considering what initiatives or projects would make good use of civil money penalty funds collected from Medicare facilities and would best benefit nursing home residents, CMS may conclude that the State is in the best position to provide that effort. In this instance, CMS is free to use its share of the collected funds to pay the State to perform those activities that CMS determines would best benefit nursing home residents. This payment to a State to secure the State's assistance for a CMS-approved resident benefit activity does not constitute an increase in the State's proportion of any civil money penalty funds collected from a dually participating facility. Rather, these are funds that CMS collected from a Title XVIII facility and which CMS subsequently determines can be used in the most beneficial way through the State.

We wish to reiterate that use of funds collected from a SNF, SNF/NF, or NF-only facility as a result of a CMS-imposed civil money penalty must be approved by CMS. We expect that CMS will issue guidance that will permit specific categories of civil money penalty use without waiting for per-request approval, while other uses not listed in the guidance would require case-by-case advance approval.

III. Collection of Information Requirements

Section 4204(b) and 4214(d) of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87), Public Law 100–203, enacted on December 21, 1987, provides a waiver of Office of Management and Budget review of information collection requirements for the purpose of implementing the nursing home reform amendments. The provisions of OBRA '87 that exempt agency actions to collect information from States or facilities relevant to survey and enforcement activities from the Paperwork Reduction Act are not time-limited.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, 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 comments in the preamble to that draft.

V. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 1993), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small business. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7 million to $34.5 million in any one year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Core-Based Statistical Area (for Medicaid) and outside of a Metropolitan Statistical Area (for Medicare) and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2010, that threshold level is currently approximately $135 million. These regulatory proposals would have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation would not impose costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

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 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR part 488 as set forth below:

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

1. The authority citation for part 488 is revised to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act, unless otherwise noted (42 U.S.C. 1302 and 1395(hh)); Section 6111 of the Patient Protection and Affordable Care Act (Pub. L. 111–148)

Subpart E—Survey and Certification of Long-Term Care Facilities

2. Revise § 488.330(e)(2)(ii) to read as follows:

§ 488.330 Certification of compliance or noncompliance.

* * * * *

(e) * * *

(2) * * *

(ii) Except for civil money penalties imposed on NFs-only by the State, during any pending hearing that may be requested by the provider of services.

* * * * *

3. Amend § 488.331 by adding a new paragraph (a)(3) to read as follows:

§ 488.331 Informal dispute resolution.

(a) * * *

(3) For SNFs, SNF/NFs, and NF-only facilities that have civil money penalties imposed by CMS, CMS offers the facility an opportunity, at the facility's request if requested within 30 days of the notice of imposition of a civil money penalty, for independent informal dispute resolution, as specified in § 488.431(a).

* * * * *

Subpart F—Enforcement of Compliance for Long-Term Care Facilities With Deficiencies

4. Section 488.400 is revised to read as follows:

§ 488.400 Statutory basis.

Sections 1819(h) and 1919(h)of the Act specify remedies that may be used by the secretary or the State respectively when a SNF or a NF is not in substantial compliance with the requirements for participation in the Medicare and Medicaid programs. These sections also provide for ensuring prompt compliance and specify that these remedies are in addition to any other available under State or Federal law, and, except, for civil money penalties imposed on NFs-only by the State, are imposed prior to the conduct of a hearing.

5. Add a new § 488.431 to read as follows:

§ 488.431 Civil money penalties imposed by CMS and independent informal dispute resolution: for SNFS, SNF/NFs, and NF-only facilities.

(a) *Opportunity for independent review.* CMS retains ultimate authority for the survey findings and imposition of civil money penalties, but provides an opportunity for independent informal dispute resolution within 30 days of notice of imposition of a civil money penalty that—

(1) Is completed within 60 days of notice of imposition of civil money penalty if an independent informal dispute resolution is timely requested by the facility.

(2) Generates a written record prior to the collection of the penalty.

(3) Includes notification to an involved resident or resident representative, as well as state ombudsman, to provide opportunity for written comment.

(4) Is conducted at the facility's expense, consistent with a user fee system approved by CMS that is designed to cover only actual expenses of the independent informal dispute resolution process based on average costs that are uniformly applied but may vary by key categories such as time used in the dispute resolution process and the average cost for the amount of time used, except that the fee shall be returned in the event that the applicable civil money penalty is completely eliminated.

(5) Is conducted by the State under section 1864 of the Social Security Act, or by an entity approved by the State and CMS, or by CMS in the case of surveys conducted only by federal surveyors, which has no conflict of interest, such as:

(i) A component of an umbrella State agency provided that the component is organizationally separate from the State survey agency.

(ii) An independent entity with healthcare experience selected by the State and approved by CMS.

(iii) A distinct part of the State survey agency, so long as the individuals conducting the independent informal dispute resolution have no conflict of interest and have not directly participated in the survey that is the subject of the dispute resolution process.

(b) *Collection and placement in escrow account.*

(1) For both per day and per instance civil money penalties, CMS may collect and place the imposed civil money penalties in an escrow account on whichever of the following occurs first:

(i) The date on which the independent informal dispute resolution process is completed under paragraph (a) of this section.

(ii) The date that is 90 days after the date of the notice of imposition of the penalty.

(2) For collection and placement in escrow accounts of per day civil money penalties, CMS may collect the portion of the per day civil money penalty that has accrued up to the time of collection as specified in paragraph (b)(1) of this section. CMS may make additional collections periodically until the full amount is collected, except that the full balance must be collected once the facility achieves substantial compliance or is terminated from the program and CMS determines the final amount of the civil money penalty imposed.

(c) *Maintenance of escrowed funds.* CMS will maintain collected civil money penalties in an escrow account pending the resolution of an administrative appeal. CMS will retain escrow funds on an on-going basis and, once a final administrative decision is made, will either return applicable funds in accordance with § 488.431(e) or, in the case of unsuccessful administrative appeals, will periodically disburse the funds to States or other entities in accordance with § 488.433.

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

(1) A facility must request a hearing on the determination of the noncompliance that is the basis for imposition of the civil money penalty within the time specified in § 498.40 of this chapter.

(2) If the administrative law judge reverses the civil money penalty determination in whole or in part, the escrowed amounts continue to be held pending expiration of the time for CMS to appeal the decision or, where CMS does appeal, a Departmental Appeals Board decision affirming the reversal of the civil money penalty. Any collected civil money penalty amount owed to the facility based on a final administrative decision will be returned to the facility with applicable interest.

6. Amend § 488.432 by revising the section heading and revising paragraphs (a), (b)(1) introductory text, (b)(2),(c)(1) introductory text, and (c)(2); and removing paragraph (e) to read as follows:

§ 488.432 Civil money penalties imposed: NF-only when State imposes civil money penalty.

(a) *When a facility requests a hearing.* (1) When the state imposes a civil money penalty against a non-state operated NF that is not subject to imposition of remedies by CMS, the NF must request a hearing on the determination of noncompliance that is the basis for imposition of the civil money penalty within the time specified in § 431.153 of this chapter.

(2)(i) If a facility requests a hearing within the time frame specified in paragraph (a)(1) of this section, for a civil money penalty imposed per day, the State initiates collection of the penalty when there is a final administrative decision that upholds 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, the State initiates collection of the penalty when there is a final administrative decision that upholds 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, the State initiates collection of the penalty when the facility—

* * * * *

(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, 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, the State initiates collection of the penalty when the facility—

* * * * *

(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, the State initiates collection of the penalty upon receipt of the facility's notification.

* * * * *

7. Add a new § 488.433 to read as follows:

§ 488.433 Civil money penalties: Uses and approval of civil money penalties imposed by CMS.

Fifty percent of the collected civil money penalty applicable to Title XVIII will be deposited with the Department of Treasury in accordance with § 488.442(f). The remaining collected civil money penalty funds may not be used for survey and certification operations but must be used entirely for activities that protect or improve the quality of care for residents. These activities must be approved by CMS and include, but are not limited to:

(a) Support and protection of residents of a facility that closes (voluntarily or involuntarily).

(b) Time-limited expenses incurred in the relocation of residents to home and community-based settings or another facility when a facility is closed (voluntarily or involuntarily) or downsized pursuant to an agreement with the state Medicaid agency.

(c) Projects that support resident and family councils and other consumer involvement in assuring quality care in facilities.

(d) Facility improvement initiatives approved by CMS, such as joint training of facility staff and surveyors or technical assistance for facilities implementing quality assurance and performance improvement program.

(e) Development and maintenance of temporary management or receivership capability such as but not limited to, recruitment, training, retention or other system infrastructure expenses. However, as specified in § 488.415(c), a temporary manager's salary must be paid by the facility.

8. Section 488.436 is amended by revising paragraph (b)(1) to read as follows:

§ 488.436 Civil money penalties: Waiver of hearing, reduction of penalty amount.

* * * * *

(b) * * *

(1) If the facility waives its right to a hearing in accordance with the procedures specified in paragraph (a) of this section, CMS or the State reduces the civil money penalty by 35 percent, as long as the civil money penalty has not also been reduced by 50 percent under § 488.438.

* * * * *

9. Section 488.438 is amended by revising paragraphs (c) and (d)(1) to read as follows:

§ 488.438 Civil money penalties: Amount of penalty.

* * * * *

(c) *Decreased penalty amounts.*

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

(2) When CMS determines that a SNF, SNF/NF, or NF-only facility subject to a civil money penalty imposed by CMS self-reports and promptly corrects the noncompliance for which the civil money penalty was imposed, CMS will reduce the amount of the penalty imposed by 50 percent, provided that all of the following apply—

(i) The facility self-reported the noncompliance to the State or CMS before it was identified by the State or CMS and before it was reported to the State or CMS by means of a complaint lodged by a person other than an official representative of the nursing home;

(ii) Correction of the self-reported noncompliance occurred within 10 calendar days of the date that the facility identified the noncompliance;

(iii) The facility waives its right to a hearing under § 488.436;

(iv) The noncompliance that was self-reported and corrected did not constitute a pattern of harm, widespread harm, immediate jeopardy, or result in the death of a resident; and,

(v) The civil money penalty was not imposed for a repeated deficiency that received a civil money penalty reduction under this section within the previous year. "Repeat deficiency" is defined in § 488.438(d)(3).

(3) Under no circumstances will a facility receive both the 50 percent civil money penalty reduction for self-reporting and correcting under this section and the 35 percent civil money penalty reduction for waiving its right to a hearing under § 488.436.

(d) *Increased penalty amounts.* (1) Before a hearing requested in accordance with § 488.431(d) or § 488.432(a), CMS 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.

* * * * *

10. Section 488.440 is amended by revising paragraphs (b) and (c) to read as follows:

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

* * * * *

(b) The per day civil money penalty is computed and collectible, as specified in § 488.431 and § 488.432, for the number of days of noncompliance until the date the facility achieves substantial compliance, or, if applicable, the date of termination.

(c)(1) For NFs-only subject to civil money penalties imposed by the State, 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.

(2) For SNFs, SNF/NFs, or NFs subject to civil money penalties imposed by CMS, collection would be in accordance with § 488.431(b).

* * * * *

11. Section 488.442 is amended to remove and reserve paragraph (b) and revise paragraphs (a), (e)(1), and (f) 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.* (1) A civil money penalty payment is due in accordance with § 488.431 of this chapter for CMS-imposed penalties and is due 15 days after the State initiates collection pursuant to § 488.432 of this chapter for State-imposed penalties, except as provided in paragraphs (a)(2) and (3) of this section.

(2) *After a request to waive a hearing.* A civil money penalty is due 15 days after receipt of the written request to waive a hearing in accordance with § 488.436.

(3) *After the effective date of termination.* A civil money penalty payment is due 15 days after the effective date of termination, if that is earlier than the date contained in subsection (a)(1).

* * * * *

(b) [Reserved]

* * * * *

(e) * * *

(1) Medicare-participating facilities are deposited and disbursed in accordance with § 488.433; and

* * * * *

(f) *Collection from dually participating facilities.* Civil money penalties collected from dually participating facilities are deposited and disbursed in accordance with § 488.433 and returned to the State in proportion commensurate with the relative proportions of Medicare and Medicaid beds at the facility actually in use by residents covered by the respective programs on the date the civil money penalty begins to accrue.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

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

Dated: May 27, 2010.

Marilyn Tavenner,

Acting Administrator and Chief Operating Officer, Centers for Medicare & Medicaid Services.

Approved: June 29, 2010.

Kathleen Sebelius,

Secretary.

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