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Medicare and Medicaid Programs; Civil Money Penalties for Nursing Homes; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

42 CFR Part 488

[CMS–2435–F]

Medicare and Medicaid Programs; Civil Money Penalties for Nursing Homes

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

ACTION: Final rule.

SUMMARY: This final rule will 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 section 6111 of the Affordable Care Act of 2010.

DATES: These regulations are effective on January 1, 2012.

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

SUPPLEMENTARY INFORMATION:

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. 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 Part 488, Subpart F, and the provisions directly affecting civil money penalties are set forth at § 488.430 through § 488.444. In the proposed rule, published on July 12, 2010, preceding this final regulation, we discussed in more detail civil money penalties for facility's noncompliance, a facility's option to dispute cited deficiencies and the facility's right to waive a hearing within specified timeframes and procedures (75 FR 39641).

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. Summary of the Proposed Provisions and Responses to Comments on the Proposed Rule

A. Overview

In the July 12, 2010 **Federal Register** (75 FR 39641), we published a proposed rule to 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 response to the proposed rule, we received approximately 213 public comments. We received comments from various States, health care associations, nursing homes, individuals, provider advocacy organizations and consumer advocacy organizations. The comments for this proposal ranged from general support of or general opposition to the proposal to more specific comments regarding the proposed rule.

In this final rule we provide a summary of each proposed provision, a summary of the public comments received, our responses to them, and any changes we are implementing in this final rule as a result of comments received.

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 Social Security Act (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.

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. They also seek to 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 proposed to revise Part 488 by adding new § 488.431 and § 488.433. We also proposed revisions to existing regulations throughout Part 488 to further incorporate the new statutory provisions. The proposed changes would be consistent with section 6111 of the Affordable Care Act. We noted that the proposed rule would provide for the establishment of an escrow account where civil money penalties may be placed until any applicable administrative appeal processes have been completed; allow for civil money penalty reductions when facilities self-

report and promptly correct their noncompliance; in cases where civil money penalties are imposed, offer an independent informal dispute resolution process where the interests of both facilities and residents are represented and balanced; and, improve the extent to which civil money penalties collected from Medicare facilities can benefit nursing home residents. Through the proposed revisions, we intended to directly promote and improve the health, safety, and overall well-being of residents.

B. Analysis of and Response to Public Comments

1. 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).

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 civil money penalties imposed for each day of noncompliance, the penalty will not be collected until after the independent informal dispute resolution process under new section (IV)(aa) is completed, 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.B.3. of this preamble.)

In the proposed rule, we interpreted 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, permits 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 independent informal 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 would be appropriately adjusted (*i.e.* were reduced or rescinded) back to the effective date of the civil money penalty. Second, it has been CMS's 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 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 proposed 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).

i. 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 civil money penalties into escrow accounts pending the resolution of an appeal. 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 have proposed implementing 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.

ii. 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 may be kept in an escrow account pending the resolution

of any subsequent appeals. 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 have proposed at § 488.431(d)(2) that if the administrative law judge (ALJ) reverses the civil money penalty amount 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 believe these new statutory provisions contemplate not only a 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 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 regulation 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 dialogue with interested stakeholders. However, we do expect that the collection of a per day civil money penalty under this final 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.

The comments we received and our responses are set forth below.

Comment: A few commenters wanted to know who will be responsible for the collected amounts and how will it be processed and tracked.

Response: CMS will be responsible through its accounting component to oversee the collection process and the maintenance of the escrow account, while a CMS data component will maintain the system that will record and track any possible administrative appeals associated with the collected civil money penalty.

Comment: Several commenters expressed concern that the early collections and escrowing of civil money penalty amounts has the potential for disrupting the cash flow that nursing homes need to successfully operate especially in smaller facilities. Other commenters felt CMS may impose significant civil money penalties on a SNF that may not have the available resources to put the total civil money penalty amount into escrow and to pay the costs associated with a formal appeal. If the resources are unavailable and there are no alternatives to posting the full amount of the civil money penalties, the commenters argued that CMS will have effectively denied participating SNFs any meaningful opportunity to contest survey findings. Such a result would operate to deprive SNFs of their due process rights under the 5th Amendment to the U.S Constitution based upon their recognized property and liberty interest. CMS should therefore permit SNFs to enter into payment plans, to post bonds or to use other alternative approaches to secure payment and allow SNFs to freely access these options.

Response: We understand that there may be rare cases where a particular provider could have limited funds due to the financial viability of their entity. In fact, our existing regulations at § 488.438 provide that a facility's financial condition is one factor that is considered in determining the amount of the civil money penalty to be imposed. However, the commenter raises the prospect that the problem for the facility may not be so much the eventual sum total amount of civil monetary payments due, but rather the more immediate timetable for the placement of funds in escrow. Therefore, in response to the comments received, we have revised § 488.431(b) by adding a new subsection (3) that states "CMS may provide for an escrow payment schedule that differs from the collection times of paragraph (1) of this subsection in any case in which CMS determines that more time is necessary for deposit of the total civil money penalty into an escrow account, not to exceed 12 months if CMS finds that immediate payment would create substantial and undue financial hardship on the facility."

In addition, at § 488.431(b)(4), we state that "If the full civil money penalty is not placed in an escrow account within 30 calendar days from the date the provider receives notice of collection, or within 30 calendar days of any due date established pursuant to a hardship finding under paragraph (b)(3), CMS may deduct the amount of the civil money penalty from any sum then or later owed by CMS or the State to the facility in accordance with § 488.442(c)."

While we appreciate the practical financial challenges for some nursing homes in rare circumstances, we do not agree that under this rule facilities would be denied any due process. The new independent informal dispute resolution process is an option available for facilities to contest survey findings prior to the collection of civil money penalties to be placed in escrow and should reduce the chances of erroneous deprivation. This is followed by post-collection full formal hearing before the Departmental Appeals Board that has always been available for contesting the findings that led to the imposition of a civil money penalty. We believe that these two processes address any due process concerns. Furthermore, we believe that there are additional safeguards and protections available to facilities to challenge the accuracy of survey findings at various points during the survey, including interviews during the survey and the exit conference.

Comment: One commenter recommended changing "may" to "shall" in proposed § 488.431(b)(1) so that the civil money penalty is always placed in escrow when a facility requests independent informal dispute resolution. Conversely, we received several comments indicating that the statutory language appeared to be discretionary and allowed the Secretary to require that not all civil money penalties be placed in escrow.

Response: Section 6111 of the Affordable Care Act amends sections 1819(h) and 1919(h) of the Act that provide the Secretary with the broad discretion to collect and place civil money penalties into an escrow account pending resolution of any subsequent appeal. The opportunity to participate in an independent informal dispute resolution is triggered when a civil money penalty imposed against the facility is subject to being collected and placed in an escrow account prior to the resolution of an appeal. In order to phase in the new collection and escrow provisions, CMS intends to initially focus only on civil money penalties imposed as a result of the most serious deficiencies. These would be the civil

money penalties that would be subject to being placed into escrow and, subsequently, an independent informal dispute resolution process. Thus, we are revising proposed § 488.431(a) to clarify that the opportunity for independent informal dispute resolution will be offered within 30 days of the notice of the imposition of a civil money penalty that will be collected and placed into escrow. We are also revising § 488.431(b) and § 488.442 to clarify that the collection process and due date for less serious civil money penalties will be the same for civil money penalties imposed by the state; in other words, CMS will use the process that is used by the states for collecting those penalties that are not placed into escrow until CMS completely phases in the new collection process. CMS will issue further guidance at a later date regarding the collection and escrow provision as well as the companion independent informal dispute resolution process.

Comment: One commenter wanted clarification on CMS's proposed establishment of an escrow account for civil money penalties. One commenter pointed out that in the case of per day penalty, subsection (a)(1)(B)(IV)(bb) of section 6111 is explicit that "a penalty may not be imposed for any day during the period beginning on the initial day of imposition of the penalty and ending on the day on which the informal dispute process under item (aa) is completed." The NPRM states that CMS interprets this to mean that "any per day civil money penalty would be effective and continue to accrue but not be collected." A commenter asked if this means the civil money penalty is not formally imposed in the first notice to the facility. Another commenter argued that CMS ignores the quoted language, interpreting the legislation to mean that a per day penalty cannot be collected during the period between imposition of the penalty and the conclusion of the dispute resolution process, but it can continue to accrue and be collected thereafter. The commenter argued that none of the reasons CMS offers for its interpretation are compelling or supported in law, and that the goal of the survey and certification process is to verify or secure substantial compliance with federal requirements, not generate revenue. Secondly, the commenter stated that long standing positions must yield to changes in the law, that CMS has no authority to render this minimal incentive smaller still, and that if anything, the interruption in penalty accrual is incentive for CMS to provide for speedy independent review processes.

Response: The notice of the opportunity for the independent informal dispute resolution process is included in the notice of the imposition of civil money penalties, as specified in proposed § 488.431. The Affordable Care Act specifies that the right to participate in an independent informal dispute resolution process applies when a civil money penalty is imposed and collected to be placed into an escrow account pending the resolution of any subsequent appeals. To consider the civil money penalty as not being imposed until after the independent informal dispute resolution occurs would result in circular logic that could result in a facility not being able to choose to participate in the independent informal dispute resolution since it could not contend that a civil money penalty had been imposed. Consequently, we believe that the statute intends that the penalty will not be collected 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.

In addition, if a 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. This would create incentives to request an independent informal dispute resolution in every case, even when the facts or findings were not truly in dispute, simply to reduce the immediate and intended financial impact of a civil monetary penalty, a result we view as inconsistent with the purpose of strengthening the deterrent effect of such a penalty. 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 will be reduced or rescinded back to the effective date of the civil money penalty. Furthermore, Section 6111 of the Affordable Care Act does not change the existing nursing home enforcement process; rather, it adds an additional process to protect facilities from early collection of a civil money penalty based on possibly erroneous deficiency findings before exhaustion of administrative remedies. Finally, since a facility could 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 remedial effect of creating financial incentives for facilities to promptly correct and maintain compliance with program requirements. Since Congress intended to enhance 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.

Comment: Several commenters questioned the meaning of "applicable interest" in the proposed rule at § 488.431(d)(2). One commenter suggested that the rate should be defined as the current rate of judgment interest. Other commenters noted that a successful appeal will lead to a refund of the escrowed amount with interest, but the way such interest is to be calculated is not described and the disposition of interest in a failed appeal is not addressed.

Response: We propose to use the same rate of interest for escrowed civil money penalty funds as the rate the Medicare statute applies in civil actions over reimbursement disputes. Section 1878(f)(2) of the Act governs the payment of interest for providers who seek judicial review of Medicare reimbursement cases and win. This section specifies that the interest rate is equal to the rate of interest on obligations issued for purchase by the Federal Hospital Insurance Trust Fund for the month in which the civil action is filed. We propose to use the same interest rate formula here, and to use the rate in effect for the month that the civil money penalty is required to be placed in escrow. The rates for particular months are published at: <http://www.cms.gov/MedicareProgramRatesStats/>, (click "Trust Fund Interest Rates"). A Departmental Appeals Board decision affirming an administrative law judge's (ALJ's) reduction or reversal of a civil money penalty amount will result in a return of appropriate funds already placed in escrow, plus applicable interest. The disposition of interest in an unsuccessful appeal is addressed at proposed § 488.431(d)(2). If the ALJ reverses a civil money penalty in whole or in part, the escrowed amounts for civil money penalties levied on the basis of those deficiencies will continue to be held pending expiration of the time for CMS to appeal the decision. Where CMS does appeal and a Departmental Appeals Board decision affirms the reversal of the applicable

deficiency, 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.

Comment: One commenter wanted to know what the time frame is for returning collected amounts to the facility, when applicable.

Response: Any collected civil money penalty amount later determined as being owed to the facility will be returned to the facility with applicable interest after a final administrative decision. The final administrative decision is either a decision of the ALJ or the Departmental Appeal Boards (DAB) Appellate Division, or when the time to appeal has passed. We expect that funds will be returned within 90 days of any final administrative decision, which is the same timeframe given to facilities to pay a civil money penalty into an escrow account.

Comment: One commenter pointed out that the proposed regulatory text at § 488.431(c) refers to § 488.431(e) which does not exist.

Response: We appreciate this technical comment and are revising the regulatory text in this final rule at § 488.431(c) to refer to the appropriate section, which is § 488.431(d)(2).

2. 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 as defined at § 489.3, 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.

The 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 have proposed implementing 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 proposed 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 proposed 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 therefore 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 have declined 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 proposed 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 specified 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 proposed adding 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 proposed 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 repeated 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 also proposed 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 reinforced 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 proposed 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 proposed 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.

The comments we received and our responses are set forth below.

Comment: Several commenters were concerned with CMS's interpretation of the provisions governing the ability of CMS to reduce civil money penalties up to 50 percent when SNFs and certain

NFs self-report and timely correct deficiencies. A main concern was that ten days from the facility's identification of its noncompliance may not be an adequate amount of time to correct a deficiency and that CMS should instead conform to the timeframe that commenters believe was mandated by Congress, i.e. ten days from the date of imposition of a civil money penalty. In addition, many commenters felt that CMS had exceeded its authority when interpreting the statutory language.

Response: The new statutory language at 1819(h)(2)(b)(ii)(II) provides the Secretary with the discretion that she “may” reduce a civil money penalty by up to 50 percent in the case where a facility self-reports and promptly corrects a deficiency for which a penalty was imposed “not later than ten calendar days after the date of such imposition”. We agree that the statutory language provides the Secretary with the discretion to permit a longer time frame for correction than the period in our proposed regulation. We also agree that correction of self-identified problems may often require more than the proposed ten days, particularly in order to effectuate systemic changes that can prevent recurrence of the problem(s). We have therefore revised § 488.438(c)(2)(ii) to reflect that we have adjusted the timeframe for correcting a self-reported deficiency or deficiencies to be the earlier of: (a) 15 calendar days from the date of the self-reported circumstance or incident that later resulted in a finding of noncompliance, or (b) ten calendar days from the date a civil money penalty was imposed. Current regulation at 42 CFR 483.13 requires a facility to thoroughly investigate certain alleged violations and report the findings of its investigation within five working days of the incident. Using this requirement as a guideline, we believe that the 15 calendar day timeframe will provide a facility with about 7–10 calendar days to make necessary corrections after the five working day period in which facility must have completed its investigation of certain alleged violations currently specified in the regulations.

To the extent that systemic changes are required to prevent reoccurrence, the 15 day timeframe will permit more time for facilities to design and implement such systemic reform. To the extent that a facility has an effectively functioning quality assurance and performance improvement system, then 15 days is more likely to be a feasible timeframe within which to take remedial action. At this time we have

elected not to use the discretion afforded in the statute to permit an even longer time period for correction because we believe that prompt action should always be taken to resolve deficiencies. For the same reason we chose to apply the maximum reduction permitted under the statute for a civil money penalty reduction when prompt action is indeed taken, so that the final rule provides that CMS will reduce a civil money penalty (if one were imposed) by the full 50 percent, as long as the requirements specified in § 488.438(c)(2) are met.

Comment: Several commenters expressed concern that offering a 50 percent reduction for self-reporting and prompt correction would result in an increase of facilities over-reporting to “head off” civil money penalties. This would result in an increase to an already overburdened State workload.

Response: We note that the regulations at § 483.13 already require a facility to report specific actions and violations involving mistreatment, neglect or abuse, and misappropriation of resident property. While we acknowledge that offering a 50 percent reduction for self-reporting and prompt correction may result in an increase of facilities over-reporting, we expect that as facilities gain experience and knowledge regarding self-reporting any increase to the State workload will be mitigated. We also hope that any other increased reporting may be balanced by more timely and assertive corrective action by facilities, as well as improved care for residents.

Comment: Several commenters asked that we define “previous year” in the requirement that a 50 percent reduction is not allowable if the civil money penalty is being imposed for a repeated deficiency that received a civil money penalty reduction in the previous year. Another suggestion was made to eliminate “previous year” altogether and apply CMS's current definition of “repeat deficiency.”

Response: We accept the comment to eliminate “previous year” and to apply CMS's definition of “repeated deficiencies” and have revised § 488.438(c)(2)(v) accordingly. Current regulations at § 488.438(d)(3) define repeated deficiencies as “deficiencies in the same regulatory grouping of requirements found at the last survey, subsequently corrected, and again found at the next survey.” The State Operations Manual (SOM) at section 7516.3 provides further clarification that repeated deficiencies are those deficiencies in the same regulatory grouping that are found at the last standard or abbreviated standard

survey, corrected, and then found again at the next standard or abbreviated standard survey. Using this definition is consistent with both existing regulation and the Affordable Care Act time frame.

Comment: One commenter asked what role the State would have outside of its existing functions with regards to the self-reported deficiencies.

Response: The State's role with regards to receiving and processing self-reported incidents will not change. However, CMS does intend to implement system changes to CMS's Automated Survey Processing Environment (ASPEN) that will allow States to indicate when a survey is the result of self-reporting. The planned ASPEN changes will also allow a notation to be included about whether or not a 50 percent reduction was applied to a civil money penalty.

Comment: A commenter asked that when multiple per instance civil money penalties result from self-reporting, does the 50 percent reduction apply to the total, cumulative civil money penalty amount or to each individual civil money penalty instance?

Response: The 50 percent reduction will apply only to civil money penalties that meet the requirements as defined by § 488.438(c). Sections 488.438(c)(2)(iv) and (v) specify that 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, the civil money penalty was not imposed for a repeated deficiency that previously received a civil money penalty reduction under this section. Each per instance civil money penalty would be evaluated individually based on the above criteria. All civil money penalties meeting all the requirements, whether one or multiple per instance civil money penalties, would receive the 50 percent reduction.

Comment: Several commenters expressed the opinion that the 50 percent reduction would never go into effect as the corrected noncompliance at scope and severity levels of D, E and G would be considered past noncompliance which are rarely, if ever, subject to civil money penalty imposition.

Response: We agree that civil money penalties would rarely be imposed for deficiencies cited as past noncompliance at the scope and severity levels of D, E and G. In the case of deficiencies cited at the "E" level, this is considered to be a "pattern" of harm and would not be eligible for the reduction in any case. If the noncompliance is serious, although a

scope and severity level has not been determined, we want to reinforce the need for timely correction, hence the 15 day timeframe for correction of the noncompliance.

Comment: One commenter suggested that we add language indicating that, in order to be eligible for a 50 percent reduction, an additional requirement should be that "the facility must have met mandatory reporting requirements as set forth by Federal law or regulation and any pertinent State law."

Response: We concur with the commenter. We believe that a facility must have met mandatory reporting requirements as set forth by Federal and State law in order to be eligible for a 50 percent reduction and therefore, we have revised § 488.438(c)(2) by adding the following new subsection:

(vi) The facility has met mandatory reporting requirements for the incident or circumstance upon which the civil money penalty is based as required by Federal law and State laws.

Comment: One commenter expressed concern about the imposition of any civil money penalty when a facility has self-reported noncompliance. They further stated that the proper incentive to self-report should be that no punitive action will be taken (i.e., no deficiency should be cited and no civil money penalty imposed) so that the facility can openly review systems, policies and procedures, and educational needs with the goal of improving care and quality of life for and with residents.

Response: We do not agree with the commenter. To participate in the Medicare and Medicaid programs, long term care facilities must be certified as meeting Federal participation requirements. There is an expectation that providers remain in compliance with all participation requirements. The regulations emphasize the need for continual, rather than cyclical, compliance and the enforcement process mandates that policies and procedures be established to promptly remedy deficient practices and to ensure that correction is lasting. Specifically, facilities must take the initiative and responsibility for continually monitoring their own performance to sustain compliance. When, through a survey, it is determined that a facility is not meeting these minimum requirements for participation in one or both programs, enforcement remedies may be imposed in order to encourage prompt compliance with participation requirements as well as to promote the continued rendering of quality health care in a safe environment. This is regardless of whether noncompliance is

self-reported or not. It is important to note that the participation requirements are the minimum health and safety standards that providers are required to meet and failure to meet these requirements may lead to the imposition of an enforcement remedy, such as a civil money penalty. CMS and the States have a statutory responsibility to identify all noncompliance, regardless of whether or not the noncompliance was self-reported. Additionally, it is important to note that imposition of a civil money penalty for current or past noncompliance, whether or not self-reported, is not a new remedy option, but rather was established by the nursing home reform changes of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) (Pub. L. 100-203) and is a less severe alternative to termination from participation in Medicare, Medicaid or both programs.

Comment: One commenter expressed concern that the new self-reporting provision would require States to inspect a facility twice within a ten day period; once to determine noncompliance and again to determine correction. This would increase pressure on State time and resources, significantly affecting the State's survey and certification operations.

Response: In very limited circumstances, some complaints or reported incidents of noncompliance would not warrant an on-site survey, especially if an alternative method of determining the facility's compliance will suffice. For example, a facility providing verifiable, written evidence of facility repairs being completed could possibly be considered by a surveyor to be sufficient to determine that a facility indeed made the required repairs. In the proposed rule we specified that correction of a deficiency must occur within ten days of identification of the noncompliance. However, as we noted above, in this final rule we have extended this timeframe for facilities to correct self-reported noncompliance at § 488.438(c)(2)(ii) but we do not always require the State to verify correction within this same timeframe.

Comment: A few commenters argue that many States require self-reporting of events well before a facility has the opportunity to self-investigate and determine, if in fact, noncompliance has occurred.

Response: A State's own self-reporting requirements are enforced by the State and fall outside the scope of this regulation.

Comment: One commenter questioned whether the 50 percent reduction applied to State-operated facilities. They further requested that CMS consider the

possibility of adding a provision that allows for a similar reduction for facilities where the civil money penalty is State-imposed.

Response: The proposed regulation states that “When CMS determines that a SNF, SNF/NF or NF-only facility subject to a civil money penalty imposed by CMS * * * State operated facilities are eligible for this reduction only when they are subject to a civil money penalty imposed by CMS. While we appreciate the suggestion that this provision also apply when the civil money penalty is State-imposed, there is currently no statutory authority for such application.

Comment: One commenter asked for CMS to clarify whether facilities must self-report to the State survey agency or to CMS. They also asked how the Regional Offices would be notified of the self-report.

Response: As currently provided in § 483.13(c)(2), the facility would self-report to the State survey agency. The State survey agency would be responsible for notifying the appropriate CMS regional office of this self-report using currently existing procedures.

Comment: We received a few comments asking for examples of specific self-reporting case scenarios.

Response: Any specific scenarios would be fact-driven and dealt with on a case by case basis. However, additional guidance regarding self-reporting will be provided in the State Operations Manual.

Comment: A few commenters ask that we define “promptly”.

Response: As noted above, the revised proposed regulation at § 488.438(c)(2)(ii) specifies that correction of the self-reported noncompliance is considered to be prompt if it is corrected either within 15 calendar days from the date that the circumstance or incident occurred or ten calendar days from the date that the civil money penalty was imposed, whichever occurs first.

Comment: One commenter asked what safeguards would be in place to prevent facilities from misrepresenting their prompt compliance.

Response: The State survey agency will follow existing procedures and guidance for determining that a facility meets all federal participation requirements. Surveyors are trained and qualified to determine a facility’s compliance with the participation requirements and they will continue to do so. The surveyors will survey/verify whether or not a provider that self-reported a deficient practice was able to correct the practice within the specified timeframe and the State agency will inform the CMS regional office of its

findings, who will then make the decision as to whether or not an imposed civil money penalty should be reduced by 50 percent.

Comment: One commenter asked if “promptly corrected” include immediate jeopardy deficiencies that have been removed during the survey.

Response: No. If the civil money penalty is imposed for deficiencies which meet the criteria established in proposed § 488.438(c)(2), the civil money penalty will be eligible for a 50 percent reduction. If the civil money penalty was imposed for a deficiency cited at the scope and severity level of immediate jeopardy, section 6111 of the Affordable Care Act will not permit that penalty amount to be reduced by 50 percent. Section 488.438(c)(2)(iv) specifies that the noncompliance that was self-reported and corrected cannot constitute a scope and severity level of immediate jeopardy.

Comment: One commenter suggested that CMS clarify when the requirements for self-reporting trigger an investigation, that facility culpability is not automatically presumed, and that all self-reported occurrences do not result in a deficiency and imposition of a remedy.

Response: As we noted in a response above, in limited circumstances some self-reporting may not trigger a survey and/or the imposition of a remedy. Determinations about whether or not a deficiency exists will continue to be made as they are now, on a case-by-case basis.

Comment: One commenter suggested that the proposed rule did not give facilities a meaningful incentive to self-report and that it gives CMS a road map to impose penalties that CMS does not presently have.

Response: The purpose of the regulation is to give nursing homes an incentive to self-report and promptly correct suspected deficient practices. While it is true that when a nursing home self-reports there is a greater likelihood that CMS will be on notice of the possibility of deficient practices, however the determination of noncompliance and the citation of deficiencies relies on evidence and documentation. CMS must maintain the balance between its resources to address noncompliance resulting from self-reported circumstances and the ability to manage the statutorily mandated survey, certification and enforcement process.

Comment: Several commenters disagreed with the proposed rule’s assertion that a facility could not receive both a 50 percent reduction for self-reporting and prompt correction and a

35 percent reduction for waiving the right to appeal an enforcement action. They note that there is nothing in the statute that would preclude a facility from receiving both.

Response: The current 35 percent reduction for waiving the right to a hearing found at § 488.436(b) was implemented under CMS’s general rulemaking authority under § 1102 of the Act, and not as a result of a specific statutory directive. There is no evidence that Congress intended these new provisions under the Affordable Care Act to be cumulative such that a facility could possibly receive up to an 85 percent total reduction of an imposed penalty (i.e., 35 percent for waiving an appeal and 50 percent for self-reporting and prompt correction). Indeed, Congress established a specific ceiling on the penalty amount that can be reduced by the Secretary, which is “not more than 50 percent.” To interpret this provision as the commenters suggested would render the enforcement remedy of imposing a civil money penalty meaningless. The purpose of a civil money penalty, indeed of all available enforcement remedies, is to protect residents from inadequate care and to motivate providers to promptly comply with the participation requirements and provide quality services.

The new authority established under section 6111 of the Affordable Care Act provides that the reduction for self-reporting and prompt correction of noncompliance could be less than 50 percent. However, rather than utilize a lower percentage, we have exercised the full discretion permitted under the law to specify that a civil money penalty reduction will be at the full 50 percent, rather than a lesser amount, so as to provide the maximum incentive to a facility to promptly correct problems it has identified. By allowing the full 50 percent reduction, we are reinforcing the incentive for a facility to continually invest in its program evaluation and improvement. While providers are still able to choose to receive the 35 percent reduction for waiving their hearing rights under the specified procedures, this can only be done if they have not already received the 50 percent reduction provided under this rule.

Therefore, at proposed § 488.436(b)(1) we specify that in order to receive the 35 percent reduction under § 488.436, a provider shall not have received the 50 percent reduction specified by § 488.438.

Comment: One commenter suggested that CMS define “self-report” to mean a voluntary written report to the State survey agency that the facility has identified and corrected potential

noncompliance with a requirement for participation.

Response: While we appreciate the comment, the State survey agency will use its discretion to determine if and/or when information self-reported by a facility should trigger an on-site survey for determining if noncompliance exists. There may be limited circumstances where a written report may be sufficient for the State survey agency, but this does not apply to all. Self-reported incidents would be processed similar to complaints received by the State survey agency. For complaints that are not at a level of immediate jeopardy or actual harm, the state survey agency decides, based on information received about the complaint, whether to investigate the complaint on-site (i.e., conduct a survey), perform a desk review of the complaint, or refer it to a more appropriate agency.

Comment: One commenter requested that we define “repeat deficiency” to mean a repeated instance of the violation of the same regulation which formed the basis of the civil money penalty.

Response: Repeated deficiencies are defined in the regulations at § 488.438(d)(3) as “deficiencies in the same regulatory grouping of requirements found at the last survey, subsequently corrected, and found again at the next survey.” We have concluded that applying this definition to the 50 percent reduction provision would maintain maximum consistency with current Federal regulations. Facilities unwilling or unable to maintain and sustain compliance with the same participation requirements over this period of time should not be benefited by a reduced civil money penalty amount.

Comment: One commenter suggested that any civil money penalty reduction be conditioned on the facility fully cooperating with any survey and other follow-up to the self-reporting. In other words, for a facility to receive a reduction in a civil money penalty, the facility would have to promptly provide any related documentation, access to staff, and the facility staff could not misrepresent to surveyors any issue raised by the self-reporting.

Response: While we appreciate the comment, we would expect that participating facilities would be fully cooperative with the survey process whether it was triggered by self-reported information or for any other reason. Absence of evidence that prompt correction occurred and that the facility is in compliance with the applicable requirements upon which the civil monetary penalty was based would, in

and of itself, preclude CMS from granting the penalty reduction. The lack of facility cooperation in the survey process would rebound to the disadvantage of the facility itself to the extent that it impaired a positive finding of prompt self-correction and present compliance.

3. Opportunity for an Independent Informal Dispute Resolution Process.

Sections 6111(a) and (b) of the Affordable Care Act add 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, subject to (IV)(cc). When an independent informal dispute resolution is offered, such offer will be provided 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. It 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 resolution 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 have proposed that 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 proposed 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 proposed at § 488.431(a)(1) that it be completed within 60 days of the imposition of a civil money penalty if it is timely requested by the facility. We proposed at § 488.431(a)(2) that an independent informal dispute resolution will generate a written record prior to collection. 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.

We proposed 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 when civil money penalty funds are to be placed in an escrow account. 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 proposed 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 asked for comments on alternative user fee systems. We believed this arrangement was 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.

We invited 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 also solicited 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 proposed 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 proposed 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.

The comments we received and our responses are set forth below.

Comment: We received comments which reiterated that all States are currently required to provide Medicare and/or Medicaid-certified nursing homes an opportunity to participate in an informal dispute resolution process and that the criteria for this process are described in Chapter 7 of the *State Operations Manual* (CMS Pub. 100-07). One commenter maintains that the regulations regarding independent informal dispute resolution should generally mirror those of informal dispute resolution. Another commenter urged CMS to provide in the final regulations a requirement that facilities must elect either the existing informal dispute resolution process or the proposed independent informal dispute resolution process. Facilities should have only one opportunity for dispute resolution as this is already an alternative to the formal appeal procedure. The commenter suggested that the regulations should clarify that only evidence that would be permissible in a traditional informal dispute resolution may be utilized in an independent informal dispute resolution. Some commenters wrote that a facility should have one chance to elect which informal dispute resolution process it wishes to pursue and should not be allowed to switch from one to the other. Other commenters wrote that nursing homes should be allowed to choose to participate in both processes.

Response: The new independent informal dispute resolution process is an additional option available to nursing homes. This final rule does not remove or alter the existing informal process at § 488.331(a) which remains as an option for nursing homes to use to dispute cited deficiencies. We believe that the existing informal dispute resolution process is expeditious and it addresses all noncompliance issues that would affect the imposition of other enforcement remedies. Section 6111 of the Affordable Care Act requires that a new independent process be available in cases of noncompliance for which a civil money penalty was imposed and the penalty is collected and deposited in an escrow account.

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. The current informal dispute resolution process will continue to be available to nursing homes.

To assure efficiency and effectiveness in the current nursing home survey and certification process, we expect that the general procedures outlined in the *State Operations Manual* for the current informal dispute resolution process would be applicable to the new independent informal dispute resolution process. Thus, we agree that nursing homes may request dispute resolution for each survey that cites deficiencies (*State Operations Manual*, Ch. 7, section 7212). We agree with the commenter that facilities should have only one opportunity for dispute resolution for the same set of survey findings, as both the current informal process and the new independent informal processes are both intended to be an additional process to the formal appeal procedure. If the government were to allow nursing homes to request both informal dispute resolution and independent informal dispute resolution on the same set of survey findings, this would serve no meaningful purpose worthy of the added expense. We have therefore clarified the nature of this choice by revising § 488.331(a)(3) and adding new § 488.431(a)(5) to make clear that facilities may not have two opportunities at an informal dispute resolution process, except in cases where the informal dispute resolution has already been completed before a facility has received notice of a civil money imposition that will be collected and placed in an escrow account.

Analogous to the current informal dispute resolution process, the new independent informal dispute resolution process would provide the nursing home the opportunity to dispute the deficiencies that led to the imposition of a civil money penalty and not challenge any other aspect of the survey process, including severity and scope classification (with the exception of a finding of substandard quality of care or immediate jeopardy), remedies imposed by the enforcing agency, alleged failure of the survey team to comply with a requirement of the survey process, alleged inconsistency of the survey team in citing deficiencies among facilities, or alleged inadequacy or inaccuracy of the process.

Comment: We received several comments regarding the time frames for requesting and completion of the independent informal dispute

resolution process. One commenter wrote that the 60-day time period from the notice of imposition of the civil money penalty to completion of the independent informal dispute resolution process may be too restrictive because the facility has up to 30 days to request the independent dispute resolution process, leaving little time for the process to be completed. The commenter asked if CMS will consider the 60-day completion window to begin from the date that the independent informal dispute resolution was requested by the facility. Another commenter asked if the 30 days included the 10-day time frame in which the facility has to request an informal dispute resolution under the current process. One commenter wrote that the independent informal dispute resolution should be completed within the same 60-day time frame that the provider has to request a hearing. Finally, another commenter wrote that the independent informal dispute resolution should be requested within the same 10-day time frame that the provider has to submit a plan of correction.

Response: 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 and, consistent with new section (IV)(cc), the civil money penalties are subject to being placed in an escrow account. This new independent process must be offered to a facility not later than 30 days after the imposition of the civil money penalty that will be collected and placed in an escrow account. We understand the commenters' confusion with these new provisions as providers have been using the current informal dispute resolution process since its implementation in 1995. In order to reduce confusion between the two processes, and to promote consistency and efficiency within the enforcement system, we will require that the nursing home has the same 10-day time frame to request independent informal dispute resolution as that which exists for the current informal dispute resolution process. In addition, we have revised § 488.431(a)(1) to clarify that the independent informal dispute resolution process will be completed within 60 days of a facility request so long as the request is made timely by the facility.

Nursing homes will be notified of the availability of the independent informal dispute resolution in either the CMS letter transmitting the Form CMS-2567 if this letter communicates the CMS notice of imposition of a civil money penalty, or in the CMS formal notice of imposition of the civil money penalty that may occur after a subsequent revisit. If a nursing home elects independent informal dispute resolution at the first opportunity to request independent informal dispute resolution, the requirement to provide independent informal dispute resolution would be met even if a civil money penalty based on the same set of survey findings were imposed at a later point in time on the nursing home.

Comment: One commenter stated that there is nothing in the independent informal dispute resolution regulation specifying that the facility must make a choice between informal dispute resolution and independent informal dispute resolution and the timing of the two processes seems to allow for facilities to use both of them. Absent a provision requiring facilities to make a choice, the incentive would be to always request an informal dispute resolution in the hope the deficiency is removed or reduced in severity prior to having to request independent informal dispute resolution. Several commenters were confused and asked how would the process work if an independent informal dispute resolution upholds a deficiency but that same deficiency is removed during the informal dispute resolution process while the independent informal dispute resolution process is ongoing, or even after it is completed. One commenter suggested that the final regulation provide that a nursing home that requests an informal dispute resolution on a specific deficiency waives its right to subsequently request an independent informal dispute resolution on that same deficiency.

Response: We agree that facilities should have only one opportunity for dispute resolution for the same set of survey findings, as both the current informal process and the new independent informal processes are both intended to be in addition to the formal appeal procedure. If the government were to allow nursing homes to request both informal dispute resolution and independent informal dispute resolution on the same set of survey findings, this would serve no meaningful purpose worthy of the added expense. As we noted above, we have revised proposed § 488.331(a)(3) and added a new section at § 488.431(a)(5). In the development of

our operational procedures, we will also provide guidance to clarify the interplay between the two distinct processes.

Comment: One commenter asked that the regulation be separated into two parts: Independent informal dispute resolution conducted by State surveyors and independent informal dispute resolution conducted by Federal surveyors.

Response: We do not concur that the regulation regarding independent informal dispute resolution be divided into two parts based on which surveyors, State survey agency surveyors or CMS regional office surveyors, conducted the survey. To require that two separate independent informal dispute resolution processes be available would be an inefficient use of limited resources. If a nursing home is provided an opportunity to request independent informal dispute resolution as a result of a survey conducted only by federal surveyors, the independent informal dispute resolution would be conducted by an entity approved by the State and CMS, or by CMS or its agent if the State's independent dispute resolution process is not used.

Comment: One comment noted that it is unclear whether the rule requires that States offer independent informal dispute resolution services or if it only encourages States to do so. Without a requirement, many nursing facilities will likely not be afforded the opportunity for independent informal dispute resolution services.

Response: The rule at § 488.331(a)(3) establishes a requirement for independent informal dispute resolution for nursing homes that have civil money penalties imposed by CMS where such a penalty is subject to being placed in an escrow account. Section 488.431(a)(5) in the proposed rule clearly establishes that States must conduct or arrange for independent informal dispute resolution to be conducted.

Comment: One commenter asked if this rule is exempting nursing homes from the right to a free hearing.

Response: We assume that by "free hearing" the commenter is referring to the existing informal dispute resolution provided at § 488.331. The existing informal dispute resolution process provided at § 488.331 is not altered by the new regulations to provide a nursing home an opportunity for independent informal dispute resolution when a civil money penalty that will be collected and escrowed is imposed.

Comment: We received many comments noting that proposed § 488.431(a) establishes CMS's intent to

retain ultimate authority for survey and findings and imposition of civil money penalties, but that the rule does not address or specify the criteria or standards for penalty assessment that will be applied by CMS when it decides to accept or reject the dispute resolution results. One commenter recommended that CMS amend proposed § 488.431 and/or provide guidance to specify the criteria and/or standards that will be applied to the review and compliance determination resulting from the independent informal dispute resolution process. The commenter recommended that proposed § 488.431 should require notification to the provider that includes a full explanation of CMS's final determination in cases where CMS disagrees with and/or overturns dispute resolution outcomes where the provider has prevailed. Another commenter asked that CMS clarify the contents of the written record, i.e., would it be a minimal statement of the final outcome or a full narrative record including key issues of the citation, primary rebuttal of the facility, rationale and supporting references for the outcome. Another commenter asked if a letter from CMS to the facility is intended to be the written record.

Response: We appreciate the commenters' concerns regarding operational aspects of the independent informal dispute resolution process that were not included in the proposed rule. In order to give States sufficient time to develop and operationalize the provisions in this rule, we will be phasing in the provision implementing the availability of an independent informal dispute resolution process. In addition, we understand that States and CMS will need time to develop protocol and training not only for the new independent informal dispute resolution process but for all the provisions in this final rule.

Therefore, the effective date for this rule is January 1, 2012. To support consistency and efficiency within the nursing home enforcement process, CMS will strengthen this final rule by including a requirement that States submit their plan for conducting independent informal dispute resolution to CMS for approval by CMS. By doing this, CMS will be able to assure consistency among the States regarding elements of the independent informal dispute resolution process that are better suited for inclusion in the *State Operations Manual* than in regulations. To support States in developing an independent informal dispute resolution process that is responsive to the comments requesting

clarification, CMS will engage a workgroup of State survey agency and CMS regional office representatives to develop a template of key elements that an independent informal dispute resolution process would include. Key elements would include a process to assure timely completion of independent informal dispute resolution, methodology for notification, and components of the independent informal dispute resolution written record. We believe that this approach recognizes that States vary in their organizational structure, their size, their resources, and their ability to comply with the regulations through a variety of operations and procedures. Therefore, we have revised proposed § 488.431(a)(5) and renumbered it in this final rule at § 488.431(a)(4) to require that all State independent informal dispute resolution processes be approved by CMS.

CMS reviews the results of the dispute resolution processes and retains the right to be the final arbiter of accuracy and appropriateness. The exact operational procedures for doing so will be provided in the *State Operations Manual* and other CMS public communications.

Comment: One commenter described a current state informal dispute resolution process which is conducted by an umbrella State agency that is organizationally separate from the State survey agency and meets all major criteria in the proposed rules for independent informal dispute resolution. The commenter continues to note that this existing state process would require minor and few procedural changes to meet every criterion of the proposed rule. The commenter suggested adding a provision to the rule that, if a State already has an independent informal dispute resolution process that meets the requirements, the State is not required to implement a new or second informal dispute resolution process or to charge providers for the State's existing independent informal dispute resolution process.

Response: As discussed previously, we are adding a requirement to this rule that CMS will approve each State's independent informal dispute resolution process. States that already have a process in place which meets the requirements of this rule will be able to submit its process to CMS for approval. It is not our intention to require new processes if a State has an existing process in place that meets the requirements of this final rule.

Comment: One commenter wrote that during an independent review, a

recommendation is based strictly on the material provided by the facility. When a State survey agency disagrees with the recommendation, it is usually due to additional information found in the surveyor notes or copies of facility forms made at the time of the survey. An independent reviewer would not have access to these documents.

Response: We do not agree with the comment that the entity conducting the independent informal dispute resolution would not have access to the documentation necessary to make an informed decision regarding the survey findings being disputed by a nursing home. Any information relevant to the survey findings being disputed, including surveyor's notes and/or copies of facility forms, is typically discussed within the CMS Form-2567 Statement of Deficiencies. Specifics regarding the operational aspects of the independent informal dispute resolution process will be provided in the *State Operations Manual*.

Comment: The proposed rule at § 488.431(a)(3) includes notification to an involved resident or resident representative, as well as State ombudsman, to provide written comment. Some commenters noted that this provision of the proposed rule is not related to Section 6111 and appears to be outside the focus of the process, which is to determine whether a deficiency is valid. One comment recommended that CMS limit access to the new process to only the nursing homes and the applicable reviewers to ensure that nursing homes are provided with a minimum level of due process.

Response: We do not accept the comments that would exclude a resident, resident representative and/or State ombudsman from the independent informal dispute resolution process because we believe this provision is consistent with ensuring independence and accountability. In addition, the fundamental purpose of the survey and certification process is to protect beneficiaries of the program. Residents, resident representatives, and State ombudsman (who represent them) add value to the process and provide input regarding the survey findings under review during the independent informal dispute resolution process. Finally, as discussed in the Preamble of the proposed rule, 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. We consider the nursing home resident to be especially important to the process, particularly since the resident may have initiated a complaint that gave rise to a complaint investigation that resulted in the finding of a deficiency. Furthermore, nothing in section 6111 or the existing regulations expressly limits such participation by affected parties. We therefore conclude that this provision of the rule is consistent with congressional intent.

Comment: Commenters asked for specific clarification regarding the provision at § 488.431(a)(3) including providing a definition of “resident representative” as someone who has legal representation; providing anonymity for residents who may fear retaliation; and defining the written process, and the notification process. Some commenters suggested that the notification process be done by the facility, the governing body of the nursing home, or the State survey agency since that is the agency having knowledge of and contact with the involved resident. One commenter wrote that all individuals, who are impacted or could potentially be impacted, should have the opportunity to provide written comment, as should the resident and family councils of the facility. A commenter suggested that the regulations should specify that residents, families and advocates should have the right to attend and actively participate in the independent informal dispute resolution process. A commenter suggested that a face to face opportunity be provided. Other commenters offered suggestions, such as requiring nursing homes to post the independent informal dispute resolution decisions in a public place without identification of a specific resident so that all facility residents can familiarize themselves with the outcome without sacrificing anonymity; or, have the State ombudsman provide the results of the dispute resolution to residents.

Response: We appreciate the variety of comments and suggestions. We will give these comments thoughtful consideration as we develop the

operational procedures to implement the independent informal dispute resolution process and publish the process in our *State Operations Manual*. In the final rule itself, we seek to strike a balance between affording opportunities to nursing home residents that are consistent with the new law and the feasibility of a process that remains informal and can reasonably be completed in a timely manner.

Comment: One commenter noted that some States have more than one State ombudsman and that it would be helpful to have a definition of the roles and responsibilities CMS intended for “the State ombudsman” who will have the opportunity for written comment in the independent informal dispute resolution process. In line with this comment, another commenter suggested that we revise the wording of the rule to state the “State Long-Term Care Ombudsman.” One comment suggested that the regulations be amended to require that resident’s and State ombudsman’s comments be given equal consideration as the facility’s comments in independent informal dispute resolution. One commenter noted that there were not enough safeguards to ensure that the process is fair and impartial. One commenter asked if lawyers of family members and facilities could be included in the process.

Response: We believe that the provisions of this rule ensure that the independent informal dispute resolution process is fair and impartial and takes into account evidence provided not only by the facility, but by residents and/or their representatives. Both the current informal dispute resolution and the new independent informal dispute resolution processes are “informal.” Although we would not expect that lawyers of either residents or their family members would have a role in providing written comments, the regulation does not prohibit this. For more inclusive participation, including representation by lawyers, there are the formal appeal processes that remain undiminished by this new and added opportunity for timely independent informal processes. We concur with the recommendation and have revised the final rule at § 488.431(a)(3) by changing “state ombudsman” to “State’s long-term care ombudsman” so that it is consistent with § 488.325 *Disclosure of results of surveys and activities*.

Comment: In response to our request for comments on alternative user fee systems in the proposed rule, we received many varied comments regarding the provision at proposed § 488.431(a)(4) that the independent informal dispute resolution be

conducted at the facility’s expense. Commenters noted that charging a nursing home for the costs of independent informal dispute resolution, but not the current informal dispute resolution, discourages independent review in favor of the usual informal dispute resolution and a fee arrangement that requires a nursing home to pay for any part of the State survey agency’s error is simply unfair. Some commenters maintain that CMS exceeded its authority, as a user fee is not included in the statutory language, while others considered a user fee to be appropriate and desirable. Some commenters questioned how the fees would be structured, as there are many variables that come into play in the review process. Commenters asked for clarification regarding what is considered actual expenses of the process. Some commenters offered very detailed suggestions based on their experience. These suggestions include that each State survey agency contract with an independent review entity and develop a fee system based on the State-specific requirements. One commenter suggested that the fee structure and amounts should be negotiated between the State agency and the independent informal dispute resolution entity. The commenter further suggested that the individual State base fee per deficiency would be consistent in all reviews, while the actual cost per hours of review and/or type of review would reflect the severity, volume of material for review, and complexity of the case file which can vary widely. Reasonable fees should take into consideration the State-specific requirements in the independent informal dispute resolution process, including costs of: management and administrative staff, database development and utilization, State-specific report development, consistency and reliability monitoring, and training and continuing education of staff. Some commenters strongly recommend leaving the billing and receipt of payment to the independent informal dispute resolution entity. Some commenters agreed that facilities should pay while others maintained that the costs should be restored to facility operations. Commenters questioned the provision that a “Fee shall be returned in the event that the applicable civil money penalty is completely eliminated” and asked that CMS clarify how an entity that conducts independent informal dispute resolution would be paid and by whom, in the event that any fee charged to the nursing home, is returned to the nursing home. A commenter recommended a

consistent user fee system to control costs. Other commenters suggested that involving the State agency in the fees would add unnecessary costs to the State agency and could be an incentive to not cite deficiencies. One comment stated that the user fee is for the service of dispute resolution, and should in no way be based on the result or finding of the resolution process.

Response: We received many valuable comments and we appreciate the commenters' suggestions and concerns. While we do not concur with all of the comments regarding a user fee, we have determined that we must research this issue further and take into consideration all the comments we received. Therefore, we will not be requiring a mandatory user fee system at this time.

After due consideration of the comments, we have removed references to the user fee that was originally proposed as § 488.431(a)(4). Some States currently offer an independent process and charge a user fee; such processes and such user fees are not affected by this rule unless an imposed civil money penalty is subject to being placed in escrow. Upon the effective date of this rule, States may no longer charge a user fee for an independent informal dispute resolution process which is initiated under this rule due to CMS's imposition of a civil money penalty that is subject to collection and being placed in escrow pursuant to § 488.431(b).

Comment: One commenter stated that paying for the costs of this new independent informal dispute resolution process would place a burden on the Medicare Trust Fund or other public sources and that currently no funds are expended from the Federal Medicare Trust funds that directly or indirectly relate to enforcement processes or otherwise for nursing homes. The commenter stated that much inefficiency currently exists within and among the State's overall survey processes well beyond the informal dispute resolution processes that might be better controlled through enhanced oversight of the States by CMS Central and regional offices. The commenter continued that while they understand the political nature of this effort, more oversight of the current practices and processes at the State and regional CMS office level might help to alleviate financial burdens and inconsistent practices on the program overall. The commenter recommends that CMS review the average length of time and the number of surveyors involved in conducting surveys based on the purpose of the survey and outcome of the survey findings, i.e., standard health survey versus complaint

survey as data analysis of this type might help to identify efficient activities and best practices between States.

Response: We appreciate the commenters concerns regarding the need for oversight of the survey and certification process. CMS acknowledges the potential impact on the Medicare Trust Fund or other public sources. However, by taking steps to improve the quality of care, the benefits to the residents outweigh the financial burden. In addition, we will take the commenters suggestions into consideration as we anticipate future revisions to the *State Operations Manual*.

Comment: We received several comments related to proposed § 488.431(a)(5). Commenters wrote that in order for the proposed independent informal dispute resolution process to be independent and objective and to provide a minimum level of due process, it must be managed and conducted by qualified individuals wholly outside of the State survey agency. The commenters stated that two of the examples of entities appropriate for conducting an independent informal dispute resolution proposed in §§ 488.431(a)(5)(i) (a component of the umbrella State agency) and (a)(5)(iii) (a distinct part of the State survey agency) do not meet the definition of "independent", since both are parts of and/or are directly connected to the State agency that cited the noncompliance. They further noted that the unique aspects involved in examining and evaluating outcomes in nursing home residents and a specific understanding and/or healthcare experience in the field of long term care would be particularly helpful in reviewing the evidence surrounding determinations of noncompliance. Commenters suggested that the final rule elaborate further on the qualifications of the independent third party and suggested that the final regulations establish the specific training and skill set necessary for the entity to ensure that the individual conducting the process is in fact "independent" and has no conflicts of interest, yet fully understands the survey process and the permissible parameters of the independent informal dispute resolution process. One commenter urged CMS to add an Administrative Law Judge to the list of entities that could conduct independent informal dispute resolution. If CMS decides to provide additional guidance through the *State Operations Manual*, the commenter urges CMS to seek stakeholder input, including input from consumers. One commenter wrote that

having this process run by an organization that is subject to approval by the State agency or that is a distinct part of State government does not lend itself to the development of a truly independent review process. The commenter urges CMS to look at models of dispute resolution that are in use in other venues and to consider whether the Quality Improvement Organizations are equipped or could be equipped to serve in this capacity. Commenters recommended that CMS establish a process to monitor the independent informal dispute resolution entities and conduct an assessment of the impact.

Response: We have considered the commenters recommendations and suggestions and conclude that many of the comments will assist us in preparing guidance to States through the *State Operations Manual*. We disagree with the commenters that the entity described at proposed § 488.421(a)(5)(i) is not "independent" and maintain that a component of an umbrella State agency that is organizationally separate from the State survey agency would thus meet the requirement to be independent. For example, if the survey agency is located in the Department of Health and Mental Hygiene (DHMH) within a State agency and the Department of Labor, Licensing and Regulation (DLLR) is located in another part of the same State agency, we would agree that qualified persons from DLLR could be part of an independent informal dispute resolution entity. We concur with the comment that a distinct part of the State survey agency would not meet the new level of independence that we find desirable. We have therefore revised proposed § 488.431(a)(5) by renumbering it as (a)(4), by adding "Be approved by CMS and conducted by the State under section 1864 of the Act * * *," by removing subsection (iii), and by revising subsection (ii) to state:

"(ii) an independent entity with a specific understanding of Medicare and Medicaid program requirements selected by the State and approved by CMS."

Comment: We received a comment suggesting that rather than focus on a costly and time consuming "independent" appeal process, facilities should be required to go directly to the existing formal appeal process on all matters they wish to contest. The commenter notes that under the existing process, facilities are able to proceed with informal dispute resolution, spend State survey agency (and sometimes CMS) time and resources on this informal appeal, and then take advantage of the automatic 35 percent

Federal penalty reduction if they waive their right to formally appeal the determination. The commenter notes that, instead, facilities should be afforded due process through a formal appeal, or be permitted to choose the benefit of the 35 percent penalty reduction by not appealing. Since "independent" informal dispute resolutions still leaves CMS in control of the final appeal determination, the commenter believes that there is great benefit and little lost by eliminating informal dispute resolution entirely.

Response: We appreciate the comment. However, a nursing home is not required to participate in either informal dispute resolution or independent informal dispute resolution to dispute survey findings. The regulations at § 488.331 provide that a state must offer a facility the opportunity to dispute the survey findings upon receipt of the official statement of deficiencies, but that a facility must request to partake in this opportunity. Similarly, the Secretary must provide a participating nursing home with the opportunity of an independent informal dispute resolution process when a civil money penalty is imposed and collected in advance of exhausting formal appeals. The nursing home must make a choice about whether or not to participate in these processes and if it does choose to participate, it must request these processes. Further, the nursing home enforcement regulations at § 488.408 provide that a facility may appeal the certification of noncompliance leading to an enforcement remedy. Here again, the facility may choose to forego a formal appeal and accept the findings and determinations from a survey. We will monitor results of the informal dispute resolution process and examine whether the process serves as a cost-effective alternative to the more expensive formal appeals process.

Comment: One commenter questioned the statement in the preamble to the proposed rule on page 39646 that the " * * * Affordable Care Act requires that the independent process be available only in cases of noncompliance for which a civil money penalty was imposed." Sections 6111 (a) and (b) of the Affordable Care Act provide the opportunity for facilities to participate in an independent informal dispute resolution process if civil money penalties have been imposed. However, nothing in statements quoting Representative Waxman indicate or confirm the intent or necessity of an additional independent informal dispute resolution process specific to the imposition of civil money penalties.

The commenter notes that the informal dispute resolution process already required at § 488.331 and the new process triggered by the imposition of civil money penalties are equally discretionary. Both afford the opportunity for providers and surveyors to debate and resolve citations that may be questionable prior to the expenditure of time and costs associated with a formal appeal. The rationale for two distinct entities that share the same objective, but retain separate criteria and procedures, appears paradoxical. The commenter concludes that the potential result is an unfairly weighted two-tiered system that is both cumbersome and administratively overburdensome.

Response: We understand the concern of the commenter. We intend to work very closely with a workgroup of State survey agency personnel and CMS regional office representatives to assure to the degree possible that the informal dispute resolution and the independent informal dispute resolution provisions are in harmony with one another. The commenter's concern about the potential for duplicate processes also reinforces our understanding and interpretation of the law. Section 6111 adds new subsection (IV)(aa) to sections 1819(h)(2)(B)(ii) and 1919(h)(3)(C)(ii) of the Act which provides for an independent informal dispute resolution process and makes the provision "subject to (cc)." New subsection "(cc)" provides for the placement of the penalty in escrow. As a result, the law requires that the independent process is offered to facilities whenever civil money penalty funds are collected and placed in an escrow account. For penalty amounts collected under the existing process (*i.e.*, after a final administrative decision), the new independent informal dispute resolution process is not required.

Comment: One commenter inquired whether States will receive additional funding to implement the independent informal dispute resolution process?

Response: State implementation of the independent informal dispute resolution process will be addressed through the routine survey and certification budget process.

4. 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. We solicited comments on whether an acceptable use of collected fees would be to offset a portion of the cost of independent reviews.

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 proposed 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 proposed 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 specified at § 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 retained current regulations at § 488.442(f) (but proposed to amend them to include reference to § 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 proposed 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 the types of initiatives or projects that would make good use of civil money penalty funds collected from Medicare facilities and that would best benefit nursing home residents, CMS may conclude that the State is in the best position to provide that judgment. 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 pre-request approval, while other uses not listed in the guidance would require case-by-case advance approval.

The comments we received and our responses are set forth below.

Comment: Several commenters suggested using civil money penalty funds to support the frontline direct care workforce enhancement projects such as facilitating the education and credentials, tracking of the State's direct care workforce, creating a direct care worker registry, and providing improvements in the competency, education, and training standards for direct care workers, as these front line workers are responsible for the care of our elders. One commenter suggested that workforce enhancement should not require pre-approval. One commenter

supports initiatives pertaining to workplace culture change, dependent adult abuse prevention and intervention, and ombudsman and other resident advocate functions.

Response: CMS concurs with the importance of the frontline direct care workforce, such as certified nurse assistants (CNAs), in the care of our vulnerable beneficiaries and the value that workforce enhancements could contribute in improving care of the nursing home residents. We appreciate the thoughtful and detailed suggestions provided. At this time we will not be able to provide an exhaustive list or address each suggested or potential use in its entirety. We will use workgroups to develop and publish *State Operations Manual* guidance, so that CMS can provide further clarification on acceptable uses of civil money penalty funds.

Comment: Many commenters representing multiple disability groups and independent living centers support using civil money penalty funds to transition residents from nursing homes to community living and asked for civil money penalty funding to be directed to Nursing Home Transition to Community programs.

Response: Nursing home residents are those individuals who receive facility-based care. When such residents wish to relocate to another nursing home or to a community setting, it may be appropriate for civil monetary penalty funds to be used in the process of relocation, such as helping residents visit prospective care settings (including a prospective apartment of their own), and even short-term trial visits to assess the suitability of a community arrangement in advance of a final decision. However, we do not consider it appropriate for such funds to be used beyond the transition process itself or to pay for expenses for which Congress has established separate funding sources, such as section 1915(c) of the Social Security Act. Appropriate transition funds for nursing home residents will need to be evaluated on a case by case basis. The offsetting of costs for nursing home residents in the event of closure or decertification is already permitted as a time-limited allowable cost for transition to the community. We caution that civil money penalty funds are variable and collected strictly as necessary in order to ensure a facility's prompt compliance with participation requirements and conditions and are not used as a source to generate revenue. Therefore these funds should not be relied upon as a steady funding source or to sustain a particular program over an extended time period.

Comment: Several commenters asked for clarification of the proportion/division of civil money penalty funds and about the requirement for CMS approval of fund usage. Commenters expressed a concern that existing civil money penalty funds are not being used appropriately. A question was posed for clarification of the Medicaid (State) portion of civil money penalties. One commenter requests that language be revised to clarify whether State-operated facilities are included or excluded. One commenter requests that language be revised to clarify whether the “remaining collected funds” is limited to the other 50 percent of applicable Title XVII funds or whether it includes those funds applicable to Title XIX. If the intent is to include Title XIX funds, the commenter disputes the appropriateness of requiring CMS approval for use of those funds beyond existing limitations on allowable uses.

Response: We proposed at § 488.433 that 50 percent of the Title XVIII portion of collected civil money penalty amounts be used for activities that would benefit nursing home residents and that the remaining 50 percent of collected funds applicable to Title XVIII continue to be deposited to the United States Department of the Treasury (Treasury). With regard to distinguishing between the portion of civil money penalty collections for dually-participating facilities that would go to the State and the portion to be conveyed to the Treasury, the current regulations at § 488.442(f) remain intact except that we are amending the section to include reference to proposed § 488.433. Proposed section 488.442(f) specifies the formula for determining the proportion of collected civil money penalty funds that are to be returned to the State in dually participating facilities, which 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 penalty begins to accrue.” Civil money penalty amounts collected from dually-participating facilities will continue to be returned to the State (in which the facility that paid the civil money penalty is located) in the same proportion under this rule.

Civil money penalty funds returned to a State under proposed section 488.442(f) may be used by the State for any project that directly benefits facility residents, in accordance with section 1919(h)(2)(A)(ii) of the Act. CMS will have the approval authority for the use of all civil money penalty funds effective March 23, 2011. If there is

reason to believe that a State is not spending collected civil money penalties in accordance with the law or not at all, this matter should be referred to the appropriate CMS Regional Office account representative so that he or she may review this matter with the State. CMS is not accepting the comment to specify whether State-operated facilities are excluded. The use of funds from any civil money penalty imposed by CMS would be subject to § 488.433.

Comment: A few commenters expressed a strong concern about the potential for the inappropriate use of civil money penalty funds being directed back to the deficient facility. Several commenters expressed concern that civil money penalties will be used under state programs to address areas or issues that should be addressed by the nursing home under its administrative responsibility to maintain adequate standards of care, and that some provisions of care are often short cuts implemented to improve facility profitability. One commenter noted that facilities are not providing safety equipment or sufficient staffing to support basic care requirements, such as feeding, turning and repositioning, and dealing with high risk populations. One commenter stated “the permitted use of civil money penalty funds should also assure that these funds cannot be used, directly or indirectly, to increase the industry’s bottom line”. A few commenters mentioned that funds should be used for recruitment and retention efforts.

Response: CMS intends that civil money penalty funds will be used to implement programs and services that go beyond meeting minimum statutory requirements at the facility level. It is not appropriate for States to return civil money penalty funds directly to a deficient facility, since a civil money penalty used by the facility to correct the noncompliance that led to its imposition would generally not represent a sanction as it would not have any remedial effect. Further, the statute provides that the funds must benefit facility residents and not the nursing home. Hiring practices including salary, turnover, recruitment and retention are within the responsibility of the facility and are the cost of doing business. While we anticipate establishing a typology of set approved uses that will not require States to wait for CMS approval before initiating a program or enterprise, we anticipate that there will be many other proposals which will need to be evaluated on a case by case basis and will require CMS advance approval.

Comment: A few commenters felt strongly that providing “joint trainings” between provider and regulator would blur the line of distinction between the two and would not be conducive to promote correct identification of deficiencies and imposition of remedies. Another organization felt strongly that it would be beneficial for the joint training to be “standardized” for both, and yet another commenter felt that this effort should be open to a variety of stakeholders. One commenter also thought that including the Long Term Care Ombudsmen in the training would be beneficial.

Response: We believe that there are benefits for joint training between State survey agencies and nursing home providers to improve understanding of Federal requirements and to communicate specific policies and procedures. In fact, CMS has sponsored such joint trainings on a national basis dating back to the implementation of OBRA ‘87 to train both States and providers in the new health and safety requirements and enforcement rules. We appreciate the required distinction between a State surveyor and a facility and expect that joint trainings are designed so the line between provider and regulator would not be blurred. To give the optimum flexibility of such training, we do not propose standardizing the joint trainings nor do we propose to limit or to require other stakeholders in joint trainings.

Comment: More than half of the commenters propose that 90 percent of the civil money penalty funds be used to benefit facility residents with 10 percent being returned to Treasury. A couple of commenters thought that a 75/25 split would be more appropriate while several supported the 50/50 split as described. One commenter felt all 100 percent of the funds should be directed to the nursing home residents. This was one of the most frequently-raised topics, and all of the commenters who raised this issue suggested that a much higher percentage of the collected funds should be reinvested back into projects designed to directly benefit residents.

Response: The Affordable Care Act created a new permissive authority that allows the Secretary to use a portion of collected civil money penalties to benefit facility residents. This authority applies only to funds that CMS requires to be placed in escrow, and that remain after all administrative appeals have been exhausted and where the facility is unsuccessful in its appeals. In response to the overwhelming amount of comments received supporting a 90/10 split and given the new opportunity to

use Medicare civil money penalty funds to benefit and protect nursing home residents, we have revised § 488.433 to specify that for funds subject to being placed in escrow, pursuant to § 488.431, after all administrative appeals have been exhausted and where the facility is unsuccessful in its appeals, 90 percent of the collected civil money will be used for activities that benefit nursing home residents and meet the requirements as specified at § 488.433. The remaining 10 percent of the collected civil money penalty for funds subject to being placed in escrow, after all administrative appeals have been exhausted and where the facility is unsuccessful in its appeals, will be deposited with the Department of Treasury in accordance with § 488.442(f). This new provision does not apply to civil monetary penalties that are not subject to being placed in escrow in accordance with § 488.431.

Comment: Most individuals that submitted comments offered the following suggested uses for collected civil money penalties:

- Supplement the state Ombudsman program funding;
- Fund recruitment of more specialized nursing home evaluators;
- Support initiatives pertaining to workplace culture change, dependent adult abuse prevention and intervention, and ombudsman and other resident advocate functions;
- Support person centered care and culture change similar to Eden Grants;
- Transportation funding for all residents when a facility closes;
- Consider the full array of quality improvement initiatives;
- Use of palliative/end of life care; and
- Resident Advocate Functions and Resident and Family Councils.

Response: At this time CMS will not be able to provide an exhaustive list or to address each suggested or potential use in its entirety, but rather we will issue subsequent guidance and publish it in the *State Operations Manual*. This guidance will provide further clarification on specific types of uses that are pre-approved and those uses that will be evaluated on a case by case basis as well as the criteria for such evaluation. Part of the evaluation criteria will include an examination of the degree to which the intended use protects residents or pertains to other uses of civil money penalty funds provided by section 6111 of the Affordable Care Act. We will also evaluate whether the potential use of civil money penalty funds is already funded under the current Survey and Certification program or whether the

potential use of a civil money penalty requires a sustainable funding source. Promising programs and state practices have already been identified in several States under the existing requirements for use of civil money penalty funds, as described in CMS Survey & Certification (S&C) Memo 09–44 (June 19, 2009). However, we do not plan to approve uses that lock in civil monetary penalty funding to very long term programs that would create the reality or the appearance of an on-going revenue demand so strong that it could affect the judgment of the State or CMS in imposing civil monetary penalties, or to fund programs for which Congress has provided another on-going funding source.

Comment: While § 488.433(e) addresses the appropriate use of civil money penalties for the infrastructure of the temporary management remedy, one commenter does not feel this provision will help as facilities cannot afford the temporary manager salary.

Response: Although it may be true that not every nursing home provider may be able to afford to hire and institute a temporary manager, we continue to believe that the ability of a State to develop the capacity to recruit potential temporary managers can advance the overall effectiveness of the nursing home enforcement process. Thus, a State can request the use of civil money penalties to build this infrastructure.

Comment: One commenter suggested that funds be used for the State Long Term Care Ombudsmen program.

Response: Enhancement to the Long Term Care Ombudsmen program to support Resident Advocate Functions and Resident and Family Councils could be discussed in the planning stages for *State Operations Manual* guidance. However, we reiterate that we do not intend to approve civil money penalty uses that may create the reality or the appearance of an on-going revenue demand so strong that it could affect the judgment of the State or CMS in imposing civil money penalties, or to fund activities for which a nursing home is already responsible under State or Federal regulations or laws, or to fund program responsibilities for which Congress has specifically provided another on-going funding source. This is not to say that CMS would necessarily deny approval of a State's use of civil monetary penalties by its Long Term Care Ombudsman program for activities that are designed to benefit nursing home residents. We intend to develop further guidance to assist States in determining the kinds of activities that would be approved by CMS.

Comment: A commenter asked about whether or not CMS intends to publicly report the amount of civil money penalties collected and asked that it be included in the final regulation.

Response: Public reporting of particular information related to enforcement actions is addressed specifically in Section 6103 of the Affordable Care Act and directs CMS to publish relevant enforcement information.

Comment: One commenter proposed that a structured and streamlined process be created to disburse civil money penalty funds in a timely manner, to be used within 3 years, and suggested that CMS convene a workgroup to address this topic.

Response: Stakeholder input into CMS's *State Operations Manual* updates will be invaluable as we tackle implementation of the final rule, and we will seek such input.

Comment: One commenter suggested that CMS examine deficiency citation data to determine pockets of deficient practice when allocating civil money penalty funds.

Response: As part of program oversight, CMS already does examine the national and State enforcement data, including civil money penalties.

5. Additional Comments on Policy Issues

CMS received several comments that did not fall into the specific areas addressed above. The comments we received and our responses are set forth below.

Comment: One commenter suggested that no further intervention is needed for nursing homes and that insurance companies, pharmaceuticals, HMOs and CEOs be examined.

Response: OBRA '87 (Pub. L. 100–203) established requirements of Medicare and Medicaid survey and certification of nursing homes as well as the enforcement process. This law established a menu of mandatory and discretionary enforcement responses when nursing homes fail to meet participation requirements. The provisions regarding civil money penalties in the affordable Care Act augments and further enhances the existing enforcement processes and does not provide authority for the examination of other industries and areas raised by the commenter. Therefore we cannot accept this comment.

Comment: We received two comments with respect to enforcing Quality Assurance and Performance Improvement Programs in SNFs and NFs.

Response: While these comments fall outside the scope of this rule, we note that Quality Assurance and Performance Improvement Programs are specifically addressed in Section 6102 of the Affordable Care Act. Under Section 6102, the Centers for Medicare & Medicaid Services are required to promulgate regulations to carry out the provisions of section 6102. We will do so separately from this current regulation.

Comment: One commenter recommended that § 488.431(a) be revised to include the State Survey Agency and the State Medicaid Agency as entities that retain the ultimate authority to determine a facility's compliance or noncompliance with the federal nursing home requirements. Further the commenter suggested that we specifically provide that an independent informal dispute resolution (or a non-independent informal dispute resolution) does not ultimately determine compliance or noncompliance.

Response: CMS disagrees with the commenter's suggested changes, as CMS retains the ultimate authority on determining compliance and/or noncompliance with program conditions and requirements.

Comment: Regarding proposed § 488.431(a)(1), one commenter asked whether it is correct to assume and interpret that the notice of imposition of a civil money penalty will come directly from CMS, since CMS retains the ultimate authority for determining compliance and imposing enforcement remedies, and not the State agency, which only recommends a civil money penalty to CMS?

Response: As we noted in our responses to the comments above, the opportunity for independent informal dispute resolution is only available when CMS imposes the civil money penalty remedy and collects the penalty amount to be placed in an escrow account. The notice of imposition of a civil money penalty will come directly from CMS.

Comment: One commenter expressed concern that the proposed rule will complicate enforcement for States which have their own statutory fining authority.

Response: The proposed rule does not change any current remedy imposition provisions. The proposed independent informal dispute resolution process provides an opportunity for providers to dispute survey findings which lead to the imposition of a civil money penalty by CMS that may be collected and placed in an escrow account.

Comment: One commenter cited inconsistencies between CMS's Regional Offices when offering guidance to State Survey Agencies and indicated that guidance provided by one Regional Office can be contrary to the advice provided by a different Regional Office. The commenter exhorted CMS Central Office to provide greater oversight of the Regional Offices to ensure consistency among the State Survey Agencies, especially the circumstances under which civil money penalties may be imposed, or reduced. One example of inconsistency among Regional Offices is evidenced by the imposition of daily versus per instance civil money penalties. The commenter stated that their State has been the subject of misinformation promulgated by industry associations asserting that their State Survey Agency's penalties are harsher than those imposed by Survey Agencies in surrounding States. Additionally, there is no assurance that the Regional Office will impose sanctions based upon the State Survey Agency's recommendations. Fragmented authority of the State Survey Agencies and CMS can be a persistent challenge to be addressed.

Response: We appreciate the comment that greater oversight of the CMS Regional Offices by the Central Office will help ensure consistency among State survey agencies. We also agree that there should be consistency among CMS Regional Offices when offering guidance to State survey agencies. In an effort to ensure consistency, operational details of the independent informal dispute resolution process will be included as guidance in the *State Operations Manual*, and we will convene a CMS workgroup to explore additional actions that may improve consistency.

Comment: One commenter asked if there is a standard timeframe that CMS has to appeal an ALJ decision.

Response: This comment falls outside the scope of this rule which deals with informal dispute resolution and not the formal hearing process which involves an administrative law judge. However, requirements regarding the appeals and hearing procedures are located at 42 CFR Part 498.

Comment: Some commenters asked whether new model letters would be prepared, standardized and revised, and be consistent nationwide.

Response: While we are proposing that core elements for the independent informal dispute resolution process be included in the new regulations, the specific operational details including model letters are more appropriate for

inclusion in the *State Operations Manual*.

III. Provisions of the Final Regulations

In this final rule we are adopting the provisions as set forth in the July 12, 2010 proposed rule with the following revisions based on the comments received—

1. Informal Dispute Resolution

- Revised § 488.331(a)(3) to clarify a facility's choice in electing either the current informal dispute resolution process or the new independent informal dispute resolution process.

2. Civil Money Penalties Imposed by CMS and Independent Informal Dispute Resolution: for SNFS, SNF/NFs, and NF-only Facilities (§ 488.431)

- Revised § 488.431(a) by making technical changes to make language more consistent, inserting clarification of when the independent informal dispute resolution would be offered, and revising the language at § 488.431(a)(1).

- Revised § 488.431(a)(3) so that it is consistent with the requirements at § 488.325 "Disclosure of results of surveys and activities".

- Removed proposed § 488.431(4), eliminating language regarding a user fee system.

- Revised § 488.431(a)(5) and renumbered it as new (a)(4) to strengthen the requirements of States for an independent informal dispute resolution. Also, based on comments received, revised subparagraph (ii) to specify necessity for understanding Medicare/Medicaid program requirements and removed subparagraph (iii).

- Added new § 488.431(a)(5).

- Revised § 488.431(b) by adding paragraph (3) that provides the ability for CMS, at its discretion, to adjust the timing of civil money penalty payments in limited circumstances to account for cases of financial hardship.

- Revised § 488.431(b) by adding new paragraphs (3) regarding an escrow payment schedule, (4) that provides CMS recourse when a facility does not pay applicable civil money penalty funds to be placed into an escrow account within 30 calendar days from notice of assessment, and (5) which clarifies that for any civil money penalties that are not collected and placed into escrow, the collection process to be used will be the same process for state-imposed civil money penalties under § 488.432.

- Revised § 488.431(c) to provide additional minor clarification and to make a technical edit to reference the

appropriate section which is § 488.431(d)(2).

- Revised § 488.431(d)(2) to provide additional minor clarification and to define applicable interest by referencing section 1878(f)(2) of the Act.

3. *Civil Money Penalties Imposed by the State: NF-Only* (§ 488.432)

- Amend § 488.432 by revising the section heading.

4. *Civil Money Penalties: Uses and Approval of Civil Money Penalties Imposed by CMS* (§ 488.433)

- Revised introductory phrase to reflect the change in division of civil money penalty funds based on public comments and to clarify when funds will be deposited.

- Revised 488.433(d) to clarify circumstances for this use of civil money penalty funds.

5. *Civil Money Penalties: Amount of Penalty* (§ 488.438)

- Revised § 488.438(c)(2)(ii) and adding subparagraphs (A) and (B) to clarify the self reporting and correction timeframe.

- Revised § 488.438(c)(2)(v) by adding the cross-reference for the definition of “repeated deficiency”.

- Revised § 488.438(c)(2) by adding new paragraph (vi) to further clarify eligibility for a 50 percent reduction.

6. *Civil Money Penalties: Effective Date and Duration of Penalty* (§ 488.440)

- Revised § 488.440(b) to include appropriate cross reference to § 488.442 and include language that clarifies the effective date and duration of civil money penalties imposed by the state for NFs-only.

- Modified § 488.440(c) for clarity by adding reference to civil money penalties imposed by CMS that may not be collected and placed into an escrow account.

7. *Civil Money Penalties: Due Date for Payment of Penalty* (§ 488.442)

- Revised § 488.442(a)(2) to include reference to § 488.431 and to add language that clarifies the process to follow when no hearing was requested, which was inadvertently omitted in the proposed rule.

IV. Collection of Information Requirements

Sections 4204(b) and 4214(d) of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87), Public Law 100–203, enacted on December 21, 1987, provide waivers 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.

V. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), 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 Orders 13563 and 12866 direct 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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We estimate that this provision will cost between \$6 and \$15 million dollars per year to implement. Of this total cost, we estimate that this provision will result in \$5.4 million in fixed costs per year and between \$1.6 million and \$10 million in variable costs per year. This estimate assumes, based on historical data, that there will be about 2,600 civil money penalties imposed each year. Historically, nursing homes request informal dispute resolutions for about 15% of civil money penalties. Each IDR reviews 2.5 deficiencies on average. The upper bound of this cost estimate assumes that 100% of all civil money penalty impositions will result in an independent informal dispute resolution request. This rule has been designated a “significant regulatory action” although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget. This rule does not reach the \$100 million economic threshold and thus is not

considered a major rule under the Congressional Review Act.

The RFA requires agencies to analyze options for regulatory relief of small business, if a rule has a significant impact on a substantial number of small entities. 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 the Secretary has determined that this final rule will 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 604 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 the Secretary has determined that this final rule will 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 and will have no consequential effect on State, local, or tribal governments, in the aggregate, or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final 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.

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 amends 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, dually-participating SNF/NFs, and NF-only facilities that have civil money penalties imposed by CMS that will be placed in a CMS escrow account, CMS also offers the facility an opportunity for independent informal dispute resolution, subject to the terms of paragraphs (b), (c), and (d) of this section and of § 488.431. The facility must request independent informal dispute resolution in writing within 10 days of receipt of CMS's offer. However, a facility may not use the dispute resolution processes at both § 488.331 and § 488.431 for the same deficiency citation arising from the same survey unless the informal dispute resolution process at § 488.331 was completed prior to the imposition of the civil money penalty.

* * * * *

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, dually-participating 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 will be placed in escrow in accordance with paragraph (b) of this section. An independent informal dispute resolution will—

(1) Be completed within 60 days of facility's request if an independent informal dispute resolution is timely requested by the facility.

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

(3) Include notification to an involved resident or resident representative, as well as the State's long term care ombudsman, to provide opportunity for written comment.

(4) Be approved by CMS and conducted by the State under section 1864 of the Act, or by an entity approved by the State and CMS, or by CMS or its agent in the case of surveys conducted only by federal surveyors where the State independent dispute resolution process is not used, and 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 a specific understanding of Medicare and Medicaid program requirements selected by the State and approved by CMS.

(5) Not include the survey findings that have already been the subject of an informal dispute resolution under § 488.331 for the particular deficiency citations at issue in the independent

process under § 488.431, unless the informal dispute resolution under § 488.331 was completed prior to the imposition of the civil money penalty.

(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.

(3) CMS may provide for an escrow payment schedule that differs from the collection times of paragraph (1) of this subsection in any case in which CMS determines that more time is necessary for deposit of the total civil money penalty into an escrow account, not to exceed 12 months, if CMS finds that immediate payment would create substantial and undue financial hardship on the facility.

(4) If the full civil money penalty is not placed in an escrow account within 30 calendar days from the date the provider receives notice of collection, or within 30 calendar days of any due date established pursuant to a hardship finding under paragraph (b)(3), CMS may deduct the amount of the civil money penalty from any sum then or later owed by CMS or the State to the facility in accordance with § 488.442(c).

(5) For any civil money penalties that are not collected and placed into an escrow account under this section, CMS will collect such civil money penalties in the same manner as the State in accordance with § 488.432.

(c) *Maintenance of escrowed funds.* CMS will maintain collected civil money penalties in an escrow account pending the resolution of any administrative appeal of the deficiency findings that comprise the basis for the civil monetary penalty imposition. CMS will retain the escrowed funds on an on-going basis and, upon a final

administrative decision, will either return applicable funds in accordance with paragraph (d)(2) of this section or, in the case of an unsuccessful administrative appeal, 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 as specified in § 498.40 of this chapter.

(2) If the administrative law judge reverses deficiency findings that comprise the basis of a civil money penalty 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 pertinent deficiency findings. 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 as specified in section 1878(f)(2) of the Act.

■ 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 by the State: NF-only.

(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 facility 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) * * *

(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) * * *

(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, the State initiates collection of civil money penalty imposed per instance of noncompliance 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.

Ten percent of the collected civil money penalty funds that are required to be held in escrow pursuant to § 488.431 and that remain after a final administrative decision will be deposited with the Department of the Treasury in accordance with § 488.442(f). The remaining ninety percent of the collected civil money penalty funds that are required to be held in escrow and that remain after a final administrative decision 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 may 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 process of relocating 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, when such facilities have been cited by CMS for deficiencies in the applicable requirements.

(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, CMS or the State will shift the penalty amount imposed per day to the lower range.

(2) When CMS determines that a SNF, dually-participating 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 by 50 percent, provided that all of the following apply —

(i) The facility 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;

(ii) Correction of the self-reported noncompliance occurred on whichever of the following occurs first:

(A) 15 calendar days from the date of the circumstance or incident that later

resulted in a finding of noncompliance; or

(B) 10 calendar days from the date the civil money penalty was imposed;

(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;

(v) The civil money penalty was not imposed for a repeated deficiency, as defined in paragraph (d)(3) of this section, that was the basis of a civil money penalty that previously received a reduction under this section; and

(vi) The facility has met mandatory reporting requirements for the incident or circumstance upon which the civil money penalty is based, as required by Federal and State law.

(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) * * *

(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, § 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 —

(1) The determination of noncompliance is upheld after a final administrative decision for NFs-only subject to civil money penalties imposed by the state or for civil money penalties imposed by CMS that are not collected and placed into an escrow account;

(2) The facility waives its right to a hearing in accordance with § 488.436; or

(3) The time for requesting a hearing has expired and CMS or the State has not received a hearing request from the facility.

(c)(1) For NFs-only subject to civil money penalties imposed by the State and for civil money penalties imposed by CMS that may not be placed in an escrow account, 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, dually-participating SNF/NFs, or NFs subject to civil money penalties imposed by CMS, collection is made in accordance with § 488.431.

* * * * *

■ 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.* (1) Payment for a civil money penalty is due in accordance with § 488.431 of this chapter for CMS-imposed penalties and 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 or when a hearing was not requested.* Except as provided for in § 488.431, a civil money penalty is due 15 days after receipt of a written request to waive a hearing in accordance with § 488.436 or 15 days after the time period for

requesting a hearing has expired and a hearing request was not received when:

(i) The facility achieved substantial compliance before the hearing request was due; or

(ii) The effective date of termination occurs before the hearing request was due.

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

(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.

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(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: December 22, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: February 17, 2011.

Kathleen Sebelius,

Secretary.

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