(5) It is in the best interest of the government to contract with the offeror or contractor even though the conflict of interest exists and a request for waiver is approved in accordance with 48 CFR 9.503.

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

Dated: June 15, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: August 20, 2007.

Michael O. Leavitt,

Secretary.

[FR Doc. E7–22773 Filed 11–21–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 483

[CMS–2266–P]

RIN 0938–AO82

Medicare and Medicaid Programs; Waiver of Disapproval of Nurse Aide Training Program in Certain Cases and Nurse Aide Petition for Removal of Information for Single Finding of Neglect

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would permit a waiver of nurse aide training disapproval as it applies to skilled nursing facilities, in the Medicare program, and nursing facilities, in the Medicaid program, that are assessed a civil money penalty of at least $5,000 for noncompliance that is not related to quality of care. This is a statutory provision enacted by section 932 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted December 8, 2003.)

In addition, this proposed rule would codify an additional statutory provision enacted by section 4755 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33, enacted on August 5, 1997) that requires the State to establish a procedure to permit a nurse aide to petition the State to have a single finding of neglect removed from the nurse aide registry if the State determines that the employment and personal history of the nurse aide does not reflect a pattern of abusive behavior or neglect and the neglect involved in the original finding was a single occurrence.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 24, 2007.

ADDRESSES: In commenting, please refer to file code CMS–2266–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/eRulemaking.* Click on the link ''Submit electronic comments on CMS regulations with an open comment period.'' (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2266–P, P.O. Box 8017, Baltimore, MD 21244–8017.

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

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2266–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

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

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the ''Collection of Information Requirements'' section in this document.

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

FOR FURTHER INFORMATION CONTACT: Pat Miller, (410) 786–6780.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–2266–P and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.cms.hhs.gov/eRulemaking*. Click on the link ''Electronic Comments on CMS Regulations'' on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

A. Waiver of Disapproval of Nurse Aide Training Program in Certain Cases

To participate in the Medicare and or Medicaid programs, long-term care facilities must be certified as meeting Federal participation requirements. Long-term care facilities include skilled nursing facilities (SNFs) for Medicare and nursing facilities (NFs) for Medicaid. The Federal participation

requirements for these facilities are specified in regulations at 42 CFR part 483, subpart B.

Section 1864(a) of the Social Security Act (the Act) authorizes the Secretary to enter into agreements with State survey agencies to determine whether SNFs 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 the Centers for Medicare & Medicaid Services 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 impose remedies on a noncompliant facility.

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 evaluate whether the care furnished meets the assessed needs of individual residents.

Sections 1819(b)(5) and 1919(b)(5) of the Act and implementing regulations at § 483.75(e) require that all individuals employed by a facility as nurse aides must have successfully completed a nurse aide training program.

Sections 1819(f)(2) and 1919(f)(2) of the Act provide that facility-based nurse aide training could be offered either by the facility or in the facility by another entity approved by the State. In other words, a facility in good standing (that is, one that is not subject to an event that results in disapproval of a nurse aide training program) may offer a facility-based program in one of two ways: It can either conduct its own facility-based State-approved nurse aide training and have the State or a State-approved entity administer the nurse aide competency evaluation program, or it can offer the entire nurse aide training and competency evaluation program through an outside entity which has been approved by the State to conduct both components.

Further, these sections prohibit States from approving a nurse aide training and competency evaluation program or a nurse aide competency evaluation program offered by or in a SNF or NF when any of the following specified events have occurred in that facility—

- The facility has operated under a nurse staffing waiver;
- The facility has been subject to an extended or partial extended survey unless the survey shows the facility is in compliance with the participation requirements; or
- The facility has been assessed a civil money penalty of not less than $5,000, or has been subject to a denial of payment, the appointment of a temporary manager, termination, or in the case of an emergency, been closed and had its residents transferred.

Program disapproval is a required, rather than a discretionary, response whenever any of these events occur. Since facilities are required to employ nurse aides who have successfully completed a training program, when a facility loses its ability to conduct facility-based training, it must, for the duration of the 2 year program disapproval, provide the required training through either the State or another State-approved outside organization as provided by § 483.151(a). However, sections 1819(f)(2)(D) and 1919(f)(2)(D) of the Act permit a waiver for program disapproval of programs offered in (but not by) a facility if the State—

- Determines that there is no other such program offered within a reasonable distance of the facility;
- Assures that an adequate environment exists for operating the program in the facility; and
- Notifies the State Long Term Care Ombudsman of this determination and these assurances.

Section 932(c)(2)(B) of the MMA added sections 1819(f)(2)(D) and 1919(f)(2)(D) of the Act which allows the Secretary to waive a facility's disapproval of its nurse aide training program upon application of a facility if the disapproval resulted from the imposition of a civil money penalty of at least $5000 and that is not related to quality of care provided to residents in the facility.

The statutory provision being implemented in this proposed rule pertains specifically and only to the civil money penalty disapproval trigger under sections 1819(f)(2)(B)(iii)(I)(c) and 1919(f)(2)(B)(iii)(I)(c) of the Act and establishes authority for CMS to approve a facility's request to waive disapproval of its nurse aide training program when that facility has been assessed a civil money penalty of at least $5,000 for deficiencies that are not related to quality of care.

B. Nurse Aide Petition for Removal of Information for Single Finding of Neglect

The nurse aide registry is one of the tools to ensure that nursing homes are employing qualified nurse aides who are properly trained, appropriately tested, and have no adverse findings against them of abuse, neglect, or misappropriation of property. Sections 1819(e)(2) and 1919(e)(2) of the Act and the implementing regulations at § 483.156 require each State to establish and maintain a registry of nurse aides who have successfully completed a nurse aide training and competency evaluation program and have been found by the State to be competent. The nurse aide registry also includes information for any nurse aides who have had an adverse finding of abuse, neglect, or misappropriation of resident property substantiated by the State survey agency. This information must be included in the registry within 10 working days of the finding and remain in the registry permanently unless the finding was made in error, the individual was found not guilty by a court of law, or the State is notified of the individual's death. Nursing homes are required to verify with State nurse aide registries (in the State where the facility is located and in other States that may have information on the individual) that prospective nurse aide employees have not abused, neglected, or mistreated residents nor misappropriated their property. A nursing home must not employ individuals who have been found guilty of abusing, neglecting, or mistreating residents by a court of law or who have had a finding entered into the State nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of their property. Section 483.13 of the regulations provides that if there has been a finding of abuse, neglect, mistreatment of residents or misappropriation of their property entered into the nurse aide registry against a nurse aide, the nurse aide is permanently prohibited from working in a nursing home. The additional purpose of this proposed rule is to implement a legislative provision enacted as part of the BBA and included in the statutory language at sections 1819(g)(1)(D) and 1919(g)(1)(D) of the Act which reads in part, ''Removal of name from nurse aide registry.'' However, since the nurse aide registry must also include information about nurse aides who have successfully completed a nurse aide training and competency evaluation program and have been found by the State to be competent, the name of the nurse aide would not be removed completely from the registry. Rather, it is technically the removal of the single adverse finding itself against a nurse aide from the nurse

aide registry in limited circumstances under specific conditions that is contemplated.

II. Discussion of the Issues

A. Waiver of Disapproval of Nurse Aide Training Program in Certain Cases

Some participation requirements for nursing homes, if unmet and which result in the assessment of a civil money penalty of at least $5,000, results in the loss of the facility's nurse aide training program for 2 years. For example, § 483.13, Resident behavior and facility practices, requires in paragraph (a) that the resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms. Another example, § 483.25, Quality of care, requires in paragraph (c) that the facility must ensure that residents who enter the facility without pressure sores do not develop them unless they are unavoidable and that residents having pressure sores receive necessary treatment and services to promote healing, prevent infection, and prevent new sores from developing. These are facility failures of direct care-giving requirements that could compromise the facility's ability to provide quality health care services directly to residents and could lead us to conclude that the facility is not providing positive role models for the training of its nurse aides.

On the other hand, there are other participation requirements that are not directly related to the provision of hands-on health care services or to the training of nurse aides. Thus, even if unmet, these facility failures would have no direct negative impact on care furnished to residents or the facility's ability to provide a positive role model for the training of its aides regarding appropriate care for residents. For example, § 483.10, Resident rights, requires in paragraph (b)(2) that a resident or his or her legal representative, has the right, after inspecting all of his or her records, to purchase, at a cost not to exceed the community standard, photocopies of the records or any portions of them upon request, with 2 working days advance notice to the facility. Another example, § 483.12, Admission, transfer and discharge rights, requires in paragraph (a)(5) that a facility must provide notice of transfer or discharge to a resident at least 30 days before the transfer or discharge occurs. While failure to meet these requirements may subject the facility to a civil money penalty of $5,000 or more, these facility failures concern administrative and procedural requirements which are not directly related to the provision of hands-on health care services to residents, and, therefore, would not be indicative of a poor facility model for its nurse aide training program.

There is currently no regulatory distinction between care-giving and non care-giving participation requirements for purposes of the nurse aide training program disapproval. Rather, the disapproval automatically results when there is any noncompliance for which a civil money penalty of $5,000 or more is assessed.

Currently, facilities assessed a civil money penalty of at least $5,000 for noncompliance with any Federal participation requirement are prohibited from offering such a training program for a period of 2 years. The purpose of this proposed rule is to implement the legislative waiver provision enacted on December 8, 2003 as part of the MMA and which amended the Act. This revision would improve the applicability of the training disapproval requirement as it applies to assessed civil money penalty sanctions of at least $5,000, by distinguishing between facility noncompliance that warrants the training program disapproval and noncompliance that does not.

As a result of these issues, the Congress concluded that the compliance assessment and response system for nursing homes needed to be improved to distinguish between what does and does not relate to the quality of care furnished to residents for purposes of determining whether disapproval of a facility's nurse aide training program should result when assessment of a civil money penalty of at least $5,000 is the only basis for disapproving the program.

This proposed rule would implement section 932 of the MMA such that the additional consequence of program disapproval need not necessarily result if we determine that the noncompliance is not related to direct hands-on resident care, and as such, would not likely compromise the facility's ability to provide successful role modeling for its training program. However, we wish to emphasize that our authority to approve a facility's request for such a waiver does not assure that a waiver would be granted. These waiver determinations would be made by CMS upon application of a nursing facility on a case-by-case basis after considering the recommendation and facts of that case as provided by the State. We do not foresee this process of noncompliance—fact gathering, analysis, and subsequent recommendation for action to CMS for purposes of determining program disapproval waivers—as an additional workload burden for States. States currently perform these functions under their agreements with CMS when they perform survey functions. They currently evaluate facility noncompliance scope, severity, nature, and impact on residents whenever they make a determination about the seriousness of a facility's noncompliance as well as when they make enforcement remedy recommendations to CMS. This proposed rule simply acknowledges that these State activities currently occur and that they would now also be used by CMS in making nurse aide training program disapproval waiver determinations.

The plain language of the statute permits waiver of training program disapproval based on the imposition of at least a $5,000 CMP that was not related to the quality of care furnished to residents. However, it does not provide guidance for what this means. On page 776 of the Conference Report to the MMA (H.R. Rep. No. 108–391 (2003), *reprinted in* 2004 U.S.C.C.A.N. 1808, 2130), it states that, ''* * * Quality of care in such instances refers to direct, hands on care furnished to residents of a facility.'' We believe that this proposed rule proposes an appropriate and rational way to implement the legislative intent of evaluating noncompliance with ''quality of care furnished to residents'' in order to determine what impact it may have on the facility's ability to provide a positive training model to its nurse aides. In order to assess the ''quality of care being furnished to residents,'' we needed to find a way to differentiate between care-giving and non-care-giving requirements. So, for purposes of implementing this new legislative provision, we are proposing to define ''quality of care furnished to residents'' as direct care and treatment that a health care professional or direct care staff provides to a resident.

We also emphasize that a finding of noncompliance with a direct care giving requirement is not necessary in order to assess a civil money penalty of at least $5,000 or to disapprove a facility's nurse aide training program. Regardless of whether or not the noncompliance is with a direct care giving requirement, the existence of the noncompliance, itself, may result in the imposition of a civil money penalty or another remedy from the menu of available sanctions. Once a remedy or remedies are imposed, a facility's ability to provide nurse aide training is prohibited for 2 years unless a waiver is approved.

In response to a facility's request for a waiver of its nurse aide training program disapproval when a civil money penalty of at least $5,000 has been assessed, the nature of the facility's deficiencies would be evaluated to determine if they are central to furnishing direct hands-on care to residents.

''Assessed'' is defined in our *State Operations Manual*, (Pub. 100–07), section 7536 A as, ''* * * the final amount determined to be owed after a hearing, waiver of right to hearing, or settlement.''

Civil money penalties can be assessed for specific instances of noncompliance (per instance) as well as for aggregate facility noncompliance (per day), we needed a method of determining how discrete and aggregate noncompliance should be evaluated for purposes of applying this waiver provision.

When a per instance civil money penalty of at least $5,000 is assessed for noncompliance with a specific participation requirement, the evaluation of that specific deficiency's direct impact on residents is clear-cut. However, when the civil money penalty of at least $5,000 is per day, the evaluation becomes more difficult. In the latter case, all of the facility's deficiencies would need to be reviewed to determine if individually or, in total, they are indicative of an overall facility failure or inability to directly provide quality care to its residents. The resulting determination would allow us to conclude whether the facility is still likely to provide a positive nurse aide training model.

Although a single care-giving deficiency, among other non care-giving deficiencies, may result in a conclusion that the facility, overall, is providing quality care to its residents, it is also possible that the seriousness of that single facility failure could cause us to conclude otherwise. While we do not intend to provide specific detail in this rule about how to operationalize this decision making process, we will provide guidance and examples in the CMS *State Operations Manual*.

We wish to reiterate that this proposal would not automatically mandate a waiver of a nurse aide training program disapproval in cases when a civil money penalty of $5,000 or more is assessed for non care-giving noncompliance. Rather, it implements the legislative flexibility to evaluate the noncompliance in context with other factors in order for CMS to make better decisions, on a case-by-case basis, about whether or not to waive the training program disapproval.

While we do not intend to include instructions in this rule about which participation requirements would be considered to be related to the direct care and hands-on treatment that a health care professional or direct care staff provides to the resident, we have included examples of our intent earlier in this preamble and will provide operational guidance in our *State Operations Manual*. The examples we have furnished simply illustrate the distinctions we believe exist between noncompliance that realistically constitutes direct hands-on care and noncompliance that does not. We encourage public comment regarding examples or issues that should be addressed in CMS operational guidance.

In consideration of the issues described, we believe that the regulation change we propose below to implement the new legislative provision strikes a fair balance between characteristics of care that a reasonable person would expect to be indicative of quality health care services. This determination would then lead us to conclude whether the facility, despite its deficiencies, is still likely to provide a positive role model for its nurse aides.

B. Nurse Aide Petition for Removal of Information for Single Finding of Neglect

A nurse aide is defined in § 483.75 of the regulations as any individual providing nursing or nursing-related services to residents in a facility who is not a licensed health professional, a registered dietician, or someone who volunteers to provide these services without pay. Although the efforts of all nursing home staff are required to provide care to residents, the role of the nurse aide is vital. Nurse aides provide much of the direct hands-on care that residents receive and are actively involved in their daily lives. Competent and caring nurse aides are essential to providing quality care to nursing home residents. Federal regulations at 42 CFR part 483, subpart D establish standards for training nurse aides and for evaluating their competency to assure that they have the education, practical knowledge, and skills needed to care for nursing home residents. Section 483.13 of the regulations prohibits nursing homes from employing individuals who have been found guilty of abusing, neglecting, or mistreating residents by a court of law or have had a finding entered into the State nurse aide registry concerning resident abuse, neglect, or misappropriation of resident property. This information must be included in the registry within 10 working days of the finding and must remain in the registry permanently unless the finding was made in error, the individual was found not guilty by a court of law, or the State is notified of the individual's death. Nursing homes are required to verify with State nurse aide registries (in the State where the facility is located and in other States that may have information on the individual) that nurse aides they are considering for employment have not abused, neglected, or mistreated residents nor misappropriated their property.

Initially, a specific incident in one State raised a concern regarding the severe effects of an adverse finding on the nurse aide registry. This led to an examination of the current regulations and subsequently to an addition to the Act addressing one specific aspect of the existing regulations. This incident involved a nurse aide with a long and exemplary work record. While assisting a resident, the nurse aide was distracted by another work demand, and the resident fell and suffered an injury. This nurse aide was found guilty of neglect and, per the current regulations, would be barred for life from ever working in a nursing home for this isolated incident. We believe permanently barring a nurse aide from working in a nursing home in this type of circumstance is inappropriate, limited, and not the kind of abuse that the original legislation was intended to prevent. This proposed regulation incorporates statutory language at sections 1819(g)(1)(D) and 1919(g)(1)(D) (Removal of name from nurse aide registry) of the Act and requires every State to establish a procedure to permit a nurse aide to petition for removal of a finding of neglect from the registry if the State determines that the employment and personal history of the nurse aide does not reflect a pattern of abusive behavior or neglect and the neglect involved in the original finding was a single occurrence.

The determination on a petition for removal of the finding of neglect can not be made before the expiration of the 1-year period beginning on the date on which the name of the nurse aide who is petitioning for removal was added to the nurse aide registry as a result of an investigation. As long as the State's process addresses the elements specified in the regulation, States may use a variety of methods to assure compliance with this requirement. For example, some States may choose a formal process through their State legislature while other States may choose an informal process, such as sending a letter to notify the nurse aide of this opportunity to petition.

III. Provisions of the Proposed Regulation

A. Waiver of Disapproval of Nurse Aide Training Program in Certain Cases

For the reasons discussed above, we propose to redesignate the current § 483.151 (c), (d), and (e) as § 483.151 (d), (e), and (f), respectively.

We propose to add a new paragraph (c)(1) in § 483.151 where a facility may request that we waive the disapproval of its nurse aide training program when the facility has been assessed a civil money penalty of not less than $5,000 if the civil money penalty was not related to the quality of care furnished to residents in the facility. We propose to add a new paragraph (c)(2) in § 483.151 to define the term quality of care furnished to residents, as the direct hands-on care and treatment that a health care professional or direct care staff provides to a resident. We propose to add a new paragraph (c)(3) in § 483.151 to specify that any waiver of disapproval of a nurse aide training program does not waive any civil money penalty imposition.

B. Nurse Aide Petition for Removal of Information for Single Finding of Neglect

We propose to redesignate the current § 483.156(d) as § 483.156(e). We propose to add a new paragraph (d)(1) in § 483.156 to require the States to establish a procedure for permitting a nurse aide to petition for removal of a finding of neglect from the nurse aide registry if the State determines that the employment and personal history of the nurse aide does not reflect a pattern of abusive behavior or neglect and the neglect involved in the original finding was a single finding. We propose to add a new paragraph (d)(2) in § 483.156 to require that the petition for removal can not be made before the expiration of the 1-year period beginning on the date on which the name of the petitioner was added to the nurse aide registry as a result of an investigation. An individual may petition a State for review of any finding made by a State under sections 1819(g)(1)(c) or 1919(g)(1)(C) of the Act after January 1, 1995.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comments on each of these issues for the information collection requirements discussed below.

Section 483.151 State review and approval of nurse aide training and competency evaluation programs and competency evaluation programs.

Section 483.151(c)(1) states that a facility may request that CMS waive the disapproval of its nurse aid training program when the facility has been assessed a civil money penalty of not less than $5,000 if the civil money penalty was not related to the quality of care furnished to residents in the facility.

The burden associated with this requirement is the time and effort put forth by the facility to request a waiver. While this requirement is subject to the PRA, we believe it meets the exemption requirements for the PRA found at 5 CFR 1320.4(a)(2).

If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Attn.: Melissa Musotto, CMS–2266–P Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503,

Attn: Carolyn Lovett, CMS Desk Officer, (CMS–2266–P),

carolyn_lovett@omb.eop.gov. Fax (202) 395–6974.

V. Response to Comments

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

VI. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

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

The RFA requires agencies to analyze options for regulatory relief of small business. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6.5 million to $31.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA for either of these regulatory proposals because we have determined, and the Secretary certifies, that neither rule would have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act for either of these regulatory proposals because we have determined, and the Secretary certifies, that neither rule would 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. That threshold level is currently approximately $120 million. These regulatory proposals would have no consequential effect on State, local, or tribal governments or on the private sector.

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

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

List of Subjects in Part 483

Grant programs—health, Health facilities, Health professions, Health Records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

For the reasons set forth in the preamble, the Centers for Medicare and Medicaid Services would amend 42 CFR chapter IV as set forth below:

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

1. The authority citation for part 483 continues to read as follows:

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

§ 483.150 [Amended]

2. Section 483.150(a) is revised to read as follows:

§ 483.150 Statutory basis: deemed meeting or waiver of requirements.

(a) *Statutory basis.* This subpart is based on sections 1819(b)(5), 1819(f)(2), 1919(b)(5), and 1919(f)(2) of the Act, which establish standards for training nurse-aides and for evaluating their competency.

* * * * *

§ 483.151 [Amended]

3. Section 483.151 is amended by—

A. Redesignating paragraphs (c), (d), and (e) as paragraphs (d), (e), and (f), respectively.

B. Adding new paragraph (c).

The addition reads as follows:

§ 483.151 State review and approval of nurse aide training and competency evaluation programs and competency evaluation programs.

* * * * *

(c) *Waiver of disapproval of nurse aide training programs.*

(1) A facility may request that CMS waive the disapproval of its nurse aide training program when the facility has been assessed a civil money penalty of not less than $5,000 if the civil money penalty was not related to the quality of care furnished to residents in the facility.

(2) For purposes of this provision, ''quality of care furnished to residents'' means the direct hands-on care and treatment that a health care professional or direct care staff furnished to a resident.

(3) Any waiver of disapproval of a nurse aide training program does not waive any requirement upon the facility to pay any civil money penalty.

* * * * *

§ 483.156 [Amended]

4. Section 483.156 is amended by—

A. Redesignating paragraph (d) as paragraph (e).

B. Adding new paragraph (d).

The addition reads as follows:

§ 483.156 Registry of nurse aides.

* * * * *

(d) *Nurse aide petition for removal of information for a single finding of neglect.* (1) The State must establish a procedure to permit a nurse aide to petition for removal of a finding of neglect from the nurse aide registry if the State determines that both of the following conditions exist:

(i) The employment and personal history of the nurse aide does not reflect a pattern of abusive behavior or neglect.

(ii) The neglect involved in the original finding was a single occurrence.

(2) The determination on a petition for removal cannot be made before the expiration of the 1-year period beginning on the date on which the name of the petitioner was added to the nurse aide registry as a result of an investigation.

* * * * *

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

Dated: May 16, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: July 31, 2007.

Michael O. Leavitt,

Secretary.

[FR Doc. E7–22629 Filed 11–21–07; 8:45 am]

BILLING CODE 4120–01–P