DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 483

[CMS–2266–F]

RIN 0938–AO82

Medicare and Medicaid Programs; Waiver of Disapproval of Nurse Aide Training Program in Certain Cases

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

ACTION: Final rule.

SUMMARY: This final rule will permit a waiver of a 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).

DATES: Effective Date: These regulations are effective on May 24, 2010.

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

SUPPLEMENTARY INFORMATION:

I. Background

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 Medicaid and Medicare 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. Therefore, 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 program 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)(C) and 1919(f)(2)(C) 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 $5,000 and that is not related to quality of care provided to residents in the facility.

II. Summary of the Proposed Provisions and Response to Comments

In the November 23, 2007 Federal Register 72 FR 65692, we published the proposed rule entitled, “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” and provided for a 30 day comment period.

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

The statutory provisions set forth in the published proposed rule pertain specifically and only to the civil money penalty disapproval trigger under sections 1819(f)(2)(B)(i)(B) and 1919(f)(2)(B)(i)(B) of the Act and establish 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.

We received a total of 23 comments from various States, health care associations and consumer advocacy organizations. The comments for this
proposal ranged from general support or general opposition of the proposal to more specific comments regarding the new training program disapproval waiver.

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

We received nine comments on the proposed rule provision requiring 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 as found at sections 1819(g)(1)(D) and 1919(g)(1)(D) of the Social Security Act (section 4755 of the Balanced Budget Act of 1997—Pub. L. 105–33, enacted on August 5, 1997).

The thoughtful comments received on these provisions of the proposed rule necessitate that CMS take additional time to further explore the issues put forth in the comments and analyze the statute to reconsider whether regulatory action is necessary and the available options before proceeding. In the event that the Secretary determines that regulatory action is required for this issue, we will publish a new notice of proposed rulemaking. Therefore, we are not finalizing these provisions in this final rule and are removing them from this final rule at this time.

General Comments

Waiver of Disapproval of Nurse Aide Training Program in Certain Cases

Comment: One commenter suggested that CMS propose a legislative change that would remove the loss of nurse aide training as an automatic consequence to the three specified events discussed earlier in this preamble, and, instead, establish the training program disapproval as another available enforcement remedy. This commenter believes it would be more rational to create the training program disapproval as another enforcement option to be considered when deficiencies bear a relationship to the care and services that a nurse aide provides. The loss of the training program in this case would be appropriate because the facility’s deficiencies demonstrate that it is not providing a positive training model for its nurse aides.

Another commenter believes that the 2-year program disapproval period is excessive and that it impedes a facility’s ability to recruit and retain staff. This commenter is particularly concerned about the 2-year program disapproval based on a facility having a nurse staffing waiver because the “lock out” contradicts the staffing waiver criteria and it does not permit a facility to begin a training program once it has acquired the needed staff.

Response: This comment falls outside the purview of this regulation. This rule specifically pertains to permitting a waiver of a facility’s nurse aide training program disapproval when the facility is assessed a civil money penalty of at least $5,000 for noncompliance that is not related to quality of care.

Regarding the length of the disapproval period, we note that the 2-year disapproval period is a statutory provision. Such a legislative change falls outside the purview of this regulation.

Comment: One commenter suggested that the variability in the use of civil money penalties among States could create inequities in the waiver application process.

Response: Some variations may exist given the fact that these penalties are a discretionary remedy and are, therefore, not imposed with identical frequency and amount from State to State. We have expended great efforts to ensure all determinations are made as consistently as possible, particularly with civil money penalty determinations.

Comment: One commenter suggested that the word “assessed” not be used as it relates to the $5,000 civil money penalty threshold amount that enables a facility to request a training program disapproval waiver. Since “assessed” has been defined in CMS’s State Operations Manual to mean the final amount determined to be owed after a hearing, waiver of right to a hearing, or settlement, this commenter believes that it allows a facility to delay the imposition of the nurse aide training prohibition for too long. Instead, the commenter proposed that CMS redefine “assessed” to mean the final decision of CMS to impose a civil money penalty.

Response: We do not have the authority to hasten or otherwise change the timeframe in which determinations are made about nurse aide training disapproval based on imposition of civil money penalties of at least $5,000 or more. The statute is explicit that a nurse aide training program must be prohibited when a facility is “assessed” a civil money penalty of at least $5,000. Additionally, a facility has a right to appeal a certification of noncompliance that leads to an enforcement remedy, such as a civil money penalty, and/or to waive its right to a hearing which reduces the assessed penalty amount under 42 CFR 488.436(b) before the final penalty amount owed by the facility is determined. Indeed, under 42 CFR 498.3(b)(14) and (d)(10)(i), a facility may only challenge the scope and severity level of noncompliance found by CMS if a successful challenge would affect the range of the civil money penalty that could be collected by CMS or impact upon the facility’s nurse aide training program. Since various events could result in a different amount of civil money penalty “assessed” than the original amount, decisions about training program disapproval prior to knowing the final assessed penalty amount would be contrary to the intent of the statute. Nurse aide training program disapproval takes effect after a final civil money penalty amount is assessed if the amount exceeds at least $5,000.

Comment: One commenter wanted to know if a facility would still lose its nurse aide training program if it had other disapproval-causing events, even though it had a civil money penalty that qualified for a training program disapproval prior to the final assessed penalty. In other words, does each separate event, that requires nurse aide training disapproval, stand alone?

Response: Yes. This waiver does not eliminate the loss of nurse aide training based on other occurring events that also require training disapproval, such as if, within the previous 2 years, a facility is subjected to an extended (or partial extended) survey under sections 1819(g)(2)(B)(i) or 1919(g)(2)(B)(i) or when a facility has been subject to a remedy described in sections 1819(h)(2)(B)(i), or (iii), 1819(h)(4), 1919(h)(1)(B)(i) or 1919(h)(2)(A)(i), (iii) or (iv) of the Act.

Comment: One commenter wondered whether the waiver request should be submitted to the State or to CMS. This commenter also asked whether the training program disapproval waiver applies only to facilities that operate their own training program or if it also applies to facilities that serve as a training site for another program, for example, a technical college.

Response: Waivers should be submitted to the State. Waiver determinations will be made by CMS on a case-by-case basis after considering the recommendation and facts of that case as provided by the State. This point was made in the November 23, 2007 proposed rule on page 65949 in the preamble to the proposed rule and will be included in final Guidance that will be developed in collaboration with interested stakeholders.

Regarding the waiver’s applicability, the new training program disapproval
various perspectives are represented forth in this final rule. Participation of implement the regulatory provisions set develop the guidance necessary to these operational issues, we will work with all interested stakeholders to offer criteria. A few of these commenters believe that such additional direction should be provided in this final rule rather than issued as manual guidance in CMS's State Operations Manual in order to ensure appropriate public awareness and comment. Other commenters requested that stakeholders be included in developing the manual guidance.

Response: While we do not intend to include instructions in this final rule on these operational issues, we will work with all interested stakeholders to develop the guidance necessary to implement the regulatory provisions set forth in this final rule. Participation of all interested parties will ensure that the various perspectives are represented and considered.

Comment: One commenter expressed concern about the distinction that the proposed rule made between per instance civil money penalties and per day civil money penalties relative to determining how discrete and aggregate noncompliance should be evaluated in applying the waiver provision. This commenter noted that no such flexibility exists in the supporting legislation because it does not specifically differentiate between civil money penalties that are based on single, or multiple, instances of noncompliance. CMS is urged to remove the flexibility and instead require that any noncompliance with quality of care should, regardless of whether singularly or in combination with other non-quality of care noncompliance, prevent a training disapproval waiver.

Response: We do not agree with this comment. The statute refers to civil money penalties generally so it does not specifically acknowledge the two civil money penalty types, that is, the per day and per instance, nor does it preclude differentiating between them. Since civil money penalties can be assessed for specific instances of noncompliance (per instance) as well as for aggregate noncompliance (per day), we needed a method of determining how discrete and aggregate noncompliance should be evaluated for waiver approval purposes. As stated in the preamble to the proposed rule, 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 because the penalty amount is not directly attributable to any one deficiency but, instead, is for the total noncompliance of the facility. Additionally, aggregate noncompliance may be comprised of a combination of quality of care and non quality of care deficiencies as well as various levels of severity and scope. When this is the case, all of the 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 residents. A single care-giving deficiency, among other non care-giving deficiencies (none of which meet other criteria for nurse aide training disapproval), may result in a conclusion that the facility, overall, is providing quality care to its residents and therefore, is providing a positive training model for its nurse aides. However, it is also possible that the seriousness of that single facility failure, among other non care-giving deficiencies, may result in a conclusion that the facility, overall, is not providing quality care to its residents and therefore, is not providing a positive training model for its nurse aides. The ability instance as well as terminations is critical to ensure that rational and defensible conclusions can be made relative to the facility’s ability to provide quality care to its residents as well as whether the loss of its nurse aids training program is appropriate or eligible for a waiver.

Part 483—Requirements for States and Long Term Care Facilities

Section 483.151 State Review and Approval of Nurse Aide Training and Competency Evaluation Programs

We proposed to redesignate the current §483.151(c), (d), and (e) as §483.151(d), (e), and (f), respectively. We also proposed 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 proposed 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 proposed 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.

Comment: Several commenters believe that the proposed definition of “quality of care”, as direct hands-on care and treatment that a health care professional or direct care staff provides to a resident, is too limited and should be expanded to include other aspects of care and services that the facility provides to residents. These commenters contend that issues related to, for example, resident’s rights, cleanliness, and safety can impact a resident’s quality of care as significantly as those that constitute direct hands-on care and they should also preclude a training program disapproval waiver.

Response: While we do not disagree that all care and services provided by a nursing home are important, Congressional intent about what constitutes “quality of care” is made clear 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), which states that, “* * * Quality of care in such instances refers to direct, hands on care furnished to residents of a facility.” In order to address this reference, it was necessary to identify care-giving requirements that, in combination with other requirements that a health care professional or direct care staff provides to a resident. That
determination will lead to conclusions about the impact the noncompliance may have on the facility’s ability to provide a positive training model to its nurse aides. Additionally, it is important to note as we did in the preamble to the proposed rule, that noncompliance need not be in a caregiving requirement in order to be assessed a civil money penalty of at least $5,000 nor to disapprove a nurse aide training program. Noncompliance with any requirement, whether caregiving or non-care-giving, may result in the imposition of a civil money penalty or other remedy. Once a $5,000 or greater civil money penalty remedy or other triggering remedies are imposed, a facility’s ability to provide nurse aide training is prohibited for 2 years unless a waiver is approved and no other training-disapproval event has occurred.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the Federal Register and solicit public comment when 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 Paperwork Reduction Act 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 comment on each of these issues for the following information collection requirements discussed below.

Section 483.151 State Review and Approval of Nurse Aide Training and Competency Evaluation Programs

Section 483.151(c)(1) states that a facility may request that CMS waive disapproval of its nurse aide training program when a 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 as well as the time and effort for States to make determinations on each waiver request. We estimate it would take one facility 1 hour to submit a waiver and one State 1 hour to make a determination on the request. We believe that 462 facilities may potentially request a waiver annually; therefore, the total annual burden associated with this requirement is 462 hours for facilities and 462 hours for States.

As required by section 3504(h) of the Paperwork Reduction Act of 1995, we have submitted a copy of this final regulation to OMB for its review of these information collection requirements described above.

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


V. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993, as further amended), 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 (UMRA) 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 2008 that threshold was approximately $125 million. This regulatory proposal will have no consequential effect on State, local, or Tribal governments in the aggregate or by the private sector, of $127 million.

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 requirements costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation will not impose a substantial direct cost on State or local governments, preempts State, or otherwise have a Federalism implication, 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 42 CFR 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 amends 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).

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.

3. Section 483.151 is amended by—
(A) Revising the section heading.
(B) Redesignating paragraphs (c), (d), and (e) as paragraphs (d), (e), and (f) respectively.
(C) Adding new paragraph (c).

The revision and addition reads as follows:

§ 483.151 State review and approval of nurse aide training 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.

[Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Hospital Insurance; and Program No. 93.777, Medicare—Supplementary Medical Insurance Program]


Charlene Frizzera,
Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: April 12, 2010.

Kathleen Sebelius,
Secretary.

[FR Doc. 2010–8902 Filed 4–22–10; 8:45 am]
BILLING CODE 4120–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17


RIN 1018–AW42

Endangered and Threatened Wildlife and Plants; Reclassification of the Oregon Chub From Endangered to Threatened

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), are reclassifying the federally endangered Oregon chub (Oregonichthys crameri) to threatened status under the authority of the Endangered Species Act of 1973, as amended (Act). This decision is based on a thorough review of the best available scientific and commercial data, which indicate that the species’ status has improved to the point that the Oregon chub is not currently in danger of extinction throughout all or a significant portion of its range.

DATES: This final rule is effective on May 24, 2010.

ADDRESSES: Comments and materials received, as well as supporting documentation used in the preparation of this final rule, are available for inspection, by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Oregon Fish and Wildlife Office, 2600 SE 98th Avenue, Suite 100, Portland, OR 97266; (telephone 503/231–6179).

FOR FURTHER INFORMATION CONTACT:
State Supervisor, U.S. Fish and Wildlife Service, Oregon Fish and Wildlife Office (see ADDRESSES). Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800/877–8339, 24 hours a day, 7 days a week.

SUPPLEMENTARY INFORMATION:

Background
The purposes of the Act (16 U.S.C. 1531 et seq.) are to provide a means whereby the ecosystems upon which endangered and threatened species depend may be conserved and to provide a program for the conservation of those species. A species can be listed as endangered or threatened because of any of the following factors: (1) The present or threatened destruction, modification, or curtailment of its habitat or range; (2) overutilization for commercial, recreational, scientific, or educational purposes; (3) disease or predation; (4) the inadequacy of existing regulatory mechanisms; or (5) other natural or manmade factors affecting its continued existence. When we determine that protection of a species under the Act is no longer warranted, we take steps to remove (delist) the species from the Federal list. If a species is listed as endangered, we may reclassify it to threatened status as an intermediate step before delisting; however, reclassification to threatened status is not required in order to delist.

Section 3 of the Act defines terms that are relevant to this final rule. An endangered species is any species that is in danger of extinction throughout all or a significant portion of its range. A threatened species is any species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. A species includes any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife that interbreeds when mature.

Previous Federal Actions
In our December 30, 1982, Review of Vertebrate Wildlife for Listing as Endangered or Threatened Species, we listed the Oregon chub as a Category 2 candidate species (47 FR 58454). Category 2 candidates, a designation no longer used by the Service, were species for which information contained in Service files indicated that proposing to list was possibly appropriate but additional data were needed to support a listing proposal. The Oregon chub maintained its Category 2 status in both the September 18, 1985 (50 FR 37958) and January 6, 1989 (54 FR 554) Notices of Review.

On April 10, 1990, the Service received a petition to list the Oregon chub as an endangered species and to designate critical habitat. The petition and supporting documentation were submitted by Dr. Douglas F. Markle and Mr. Todd N. Pearson, both affiliated with Oregon State University. The