rebate regulation for the Medicaid drug rebate program. This document corrects the effective date.

EFFECTIVE DATE: The effective date of the August 29, 2003 final rule (68 FR 51912) amending 42 CFR part 447 is corrected from October 1, 2003 to January 1, 2004.

FOR FURTHER INFORMATION CONTACT: Marge Watchorn, (410) 786–4361.

SUPPLEMENTARY INFORMATION:

I. Background

On August 29, 2003, we published in the **Federal Register** a final rule with comment period entitled, ''Medicaid Program; Time Limitation on Price Recalculations and Recordkeeping Requirements Under the Drug Rebate Program.'' The rule establishes requirements for recordkeeping and time limits on price recalculations. The effective date of these requirements as stated in the August 2003 rule is October 1, 2003.

The Office of Management and Budget (OMB) declared that the August 2003 final rule is a major rule. Thus, we should have given January 1, 2004 as the effective date in accordance with 5 U.S.C. 801(a)(4). However, we erroneously incorporated an incorrect effective date of October 1, 2003. We have identified and corrected that error in the ''Correction of Errors'' section below.

II. Correction of Errors

In FR Doc. 03–21548 of August 29, 2003 (68 FR 51917), make the following correction:

• On page 51912, in column one, in the ''Dates'' section, remove ''October 1, 2003'' and replace it with ''January 1, 2004.''

III. Waiver of Notice of Proposed Rulemaking and Delay of the Effective Date

We ordinarily publish a general notice of proposed rulemaking in the **Federal Register** and invite prior public comment on a proposed rule. Final rules generally have a 30-day or longer prospective effective date. However, this document merely provides a correction to the effective date of the final rule with comment published on August 29, 2003. This correction is being made based on OMB's decision that the August 2003 final rule is a major rule. Thus, we should have given January 1, 2004 as the effective date in accordance with 5 U.S.C. 801(a)(4). However, we erroneously incorporated an incorrect effective date of October 1, 2003. It would be impracticable, unnecessary and contrary to the public interest to publish a proposed rule and solicit comments since this document is technical in nature and does not impose new limits on the substantive rights of the industry or the public. Similarly, given the imminence of the effective date, it would serve no useful purpose to further delay the effective date of this technical correction. Therefore, to the extent that 5 U.S.C. 553 applies to this action, we find good cause to waive notice and comment procedures and our usual delay in the effective date.

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

Dated: September 24, 2003.

Ann C. Agnew,

Executive Secretary to the Department.

[FR Doc. 03–24550 Filed 9–25–03; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 483 and 488

[CMS–2131–F]

RIN 0938–AL04

Medicare and Medicaid Programs; Requirements for Paid Feeding Assistants in Long Term Care Facilities

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

ACTION: Final rule.

SUMMARY: This final rule permits a long term care facility to use paid feeding assistants to supplement the services of certified nurse aides under certain conditions. States must approve training programs for feeding assistants using Federal requirements as minimum standards. Feeding assistants must successfully complete a State-approved training program and work under the supervision of a registered nurse or licensed practical nurse. The intent is to provide more residents with help in eating and drinking and reduce the incidence of unplanned weight loss and dehydration.

EFFECTIVE DATE: These regulations are effective on October 27, 2003.

FOR FURTHER INFORMATION CONTACT: Nola Petrovich, (410) 786–4671.

SUPPLEMENTARY INFORMATION: *Copies:* This **Federal Register** document is also available from the **Federal Register** online database through GPO access, a service of the U.S. Government Printing Office. The Web site address is *http://www.access.gpo.gov/nara/index.html.*

I. Background

Legislation

Sections 1819(a) through (e) and 1919(a) through (e) of the Social Security Act (the Act) set forth the requirements that long term care facilities must meet to participate in the Medicare and Medicaid programs, respectively. Sections 1819(f)(2) and 1919(f)(2) of the Act contain requirements for nurse aide training and competency evaluation programs (NATCEP). Sections 1819(g) and 1919(g) of the Act contain the criteria that we use to assess a facility's compliance with the requirements. These statutory provisions were mandated by the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) (Pub. L. 100–203, enacted December 22, 1987). The requirements for long term care facilities are codified at 42 CFR part 483, subpart B; the nurse aide training and competency evaluation program requirements are codified at 42 CFR part 483, subpart D; and the survey, certification and enforcement procedures are codified at 42 CFR part 488, subparts E and F.

Sections 1819(b)(5)(F) and 1919(b)(5)(F) of the Act and regulations at § 483.75(e) define a nurse aide as any individual furnishing nursing or nursing-related services to residents in a facility, who is not a licensed health professional, a registered dietitian, or someone who volunteers to provide services without pay. Sections 1819(f)(2) and 1919(f)(2) of the Act set forth the requirements for approval of a nurse aide training and competency evaluation program, but do not define ''nursing'' or ''nursing related'' skills. Section 483.152 of the regulations specifies nurse aide training requirements. These include, for example, basic nursing skills, personal care skills, communication and interpersonal skills, infection control, safety and emergency procedures, mental health and social service needs, residents' rights, care of cognitively impaired residents, and basic restorative services.

On March 29, 2002, we published in the **Federal Register** a proposed rule, ''Requirements for Paid Feeding Assistants in Long Term Care Facilities'' (67 FR 15149), that offered long-term care facilities the option to use paid feeding assistants, if consistent with State law.

Current Program Experience

Currently, there is no provision in the regulations for the use of single-task workers, such as paid feeding assistants, in nursing homes. To ensure the safety

of facility residents, we require that qualified nursing staff provide assistance with eating and drinking, although there is some question whether or not all residents need medical supervision. This group of personnel includes registered nurses, licensed practical nurses, and certified nurse aides who have completed 75 hours of training. However, volunteers, who are usually family members, may also feed residents, because the law and regulations exclude volunteers from the definition of certified nurse aide.

Nursing homes in many States report a continuing shortage of certified nurse aides.[1], [2], [3]. Nursing homes are finding it increasingly difficult to train and retain sufficient numbers of qualified nursing staff, especially certified nurse aides. Certified nurse aides perform the majority of resident care tasks. Other employers often pay similar wages for less physically and emotionally demanding jobs. This makes it harder for nursing homes to employ enough nursing staff to perform routine nursing care and to feed residents who need minimal help or just encouragement at mealtimes. Feeding residents is often a slow process and competes with more complex tasks, such as bathing, toileting, and dressing changes, as well as urgent medical care.

For many elderly nursing home residents, physical and psychological changes often interfere with eating ability and meal consumption. Residents may need assistance with feeding if they have, for example, cognitive impairment, impaired swallowing due to muscular weakness or paralysis, a tendency to aspirate or choke, poor teeth, ill-fitting dentures or partial plates, or poor muscular or neurological control of their arms or hands, as with Parkinson's disease.

Current Trends

Nursing homes are caring for an aging population that has more acute clinical conditions than in the past. The result is a higher percentage of nursing home residents who need higher levels of care, which takes more staff time and leaves less time for routine tasks, such as ensuring that residents eat their meals and drink enough fluids.

In addition, evidence suggests that there has been a recent increase in assisted living facilities that house many individuals with minimal medical needs who previously would have been cared for in nursing homes. Both of these trends have resulted in a frailer nursing home population than previously, with residents who are more dependent on nursing staff for basic needs, such as feeding and personal care. A critical shortage of certified nurse aides in many parts of the country has resulted in a need for staff who are specially trained to help residents eat at mealtimes, to supplement, not replace certified nurse aides.

Some residents only need encouragement or minimal assistance, which does not require nursing training. Properly trained non-nursing personnel could provide this type of assistance. Nurse aides and other nursing staff receive training so that they are able to feed residents with all kinds of feeding problems. A higher level of training is required of nurse aides because nurse aides need to be able to deal with complicated feeding problems. However, when there is a nurse aide shortage, it is often the case that residents without complicated feeding problems receive little or no assistance at mealtimes with eating or drinking, while the nursing staff focuses on feeding residents with complicated problems. We believe there is a place in nursing homes for the use of feeding assistants who, after proper basic training in feeding techniques and working with the elderly, are able to feed residents who do not have complicated feeding problems. It is reasonable to require that feeding assistants receive a lower level of training than a nurse aide because feeding assistants would not handle complicated feeding cases. This would allow facilities, if they choose, to train other facility employees as feeding assistants so that available staff can feed residents at mealtimes.

Facility Staff Shortages

Because of the shortage of certified nurse aides and the increasingly complex medical needs of residents, facilities in some States have used paid feeding assistants to supplement certified nurse aides to ensure that residents take in adequate food and fluids. Generally, feeding assistants used by these facilities are part-time workers, often retired individuals, or homemakers who are available for a few hours a day. They may also be older students who come into the facility between 1 and 2 hours either at the noon or evening meal. In other facilities, staff shortages are so acute that all nonmedical employees, including the administrator of the facility, are required to complete training and help feed residents at mealtimes. Training facility personnel for functions other than their primary position is known as cross-training. There is anecdotal evidence that cross-training of personnel in nursing homes increases coordination and continuity of care.[1] It also contributes to increased morale and lower staff turnover.

There is no provision in Federal regulations for the employment of nursing home workers who perform only a single task without completing 75 hours of nurse aide training. Currently, residents must be fed by a registered nurse, licensed practical nurse, or a nurse aide who has completed 75 hours of training and who has been certified as competent to perform all nurse aide tasks. Volunteers may also feed residents. The reason for this existing policy is to ensure that residents who cannot, or do not, feed themselves are fed by trained nursing staff. This is intended to protect residents from unskilled workers who might injure a resident by not recognizing serious medical complications associated with eating.

Wisconsin and North Dakota are two States in which nursing homes have had serious difficulty hiring enough certified nurse aides and have used feeding assistants as a supplement to certified nurse aides. Other States have expressed interest in using paid feeding assistants, including Ohio, Minnesota, Florida, California, and Illinois. Florida and Illinois have both passed laws that permit the use of single task workers in their States, but they have not yet implemented the provisions.

Wisconsin nursing homes have been using single-task feeding assistants for more than 7 years. Wisconsin uses a structured, formal program that requires a facility wanting to implement a feeding assistant program to submit an application for approval by the State. The classes are taught by a registered nurse, with a registered dietitian teaching the dietary elements of the program. A facility's approved program must include the following core areas: Interpersonal communication and social interaction; Basic nursing skills (including infection control); Personal care skills (assisting with eating, hydration); Basic restorative services (assistive devices for eating); Resident

[1] Stone, R.I. (2001) Frontline workers in long-term care: Research challenges and opportunities. *Generations, 25(1),* 49–57.

[2] Stone, R.I., with Weiner, J. A. (2001). *Who will care for us? Addressing the long-term care workforce crisis.* Washington, D.C: Robert Wood Johnson Foundation.

[3] United States General Accounting Office. Nursing Workforce: Recruitment and Retention of Nurses and Nurses Aides Is a Growing Problem. (Washington, DC., May 2001)

[1] Stone, R.I., Reinhard, S.C., Bowers, B., Zimmerman, D., Phillips, C.D., Hawes, C., Fielding, J.A., and Jacobson, N. (2002).*Evaluation of the Wellspring Model for Improving Nursing Home Quality.*

rights; and special problems associated with Dementia (specialized feeding and intake problems). Participants who complete the training must demonstrate skills and pass a written test with a score of 80 percent or better. Feeding assistants are used solely for feeding residents who have no feeding complications. They are permitted to feed residents only in the dining room and operate under the direction of a registered nurse or licensed practical nurse. Feeding assistants serve to supplement care delivered by certified nurse aides, which frees up more extensively trained aides to perform more complex resident care tasks.

North Dakota has used paid feeding assistants for a number of years and has a slightly less formal program than that of Wisconsin. The residents to be fed are selected by the dietary and nursing staff. If a facility has a nurse aide training program, the training coordinator and dietitian work together to train new feeding assistants individually. After training and orientation, a new feeding assistant is assigned to one resident who needs minimal assistance. As the assistant gains skill and confidence, he or she is assigned to more residents at a meal or to a resident who requires a higher level of skill to feed. Typically, feeding assistants work only about 1½ hours per day, providing assistance at either the noon or evening meal.

Conclusion

We are committed to ensuring that long term care residents receive the best possible care. We recognize that a shortage of certified nurse aides may adversely affect resident care and prevent many residents from receiving adequate help with eating and drinking. Further, we are persuaded by the experience of States that have used paid feeding assistants, that proper training and medical direction of these feeding assistants minimizes the risk to residents, while providing substantial benefits to residents. After thoroughly considering this issue, we believe that the benefits to residents outweigh the potential risks. We believe that a policy change to allow the use of feeding assistants can be accommodated under existing statute. There is nothing in the statute governing requirements for long term care facilities (sections 1819 and 1919 of the Act) that would preclude the use of these workers and we believe that there is no conflict with other statutory requirements.

II. Provisions of the Proposed Regulations

We proposed that feeding assistants must complete successfully a State-approved training course that meets minimum Federal requirements specified in proposed § 483.160. These course requirements would consist of relevant items from the nurse aide training curriculum and would include feeding techniques; assistance with feeding and hydration; communication and interpersonal skills; appropriate responses to resident behavior; safety and emergency procedures, including the Heimlich Maneuver; infection control; resident rights; and recognizing changes in residents that are inconsistent with their normal behavior, and the importance of reporting those changes to the supervisory nurse. Facilities or States may want to add items to these minimum requirements.

We proposed that each facility that uses feeding assistants maintain a record of the individuals who have successfully completed the feeding assistance training. Facilities would be required to report to the State any incidents in which a feeding assistant has been found to neglect or abuse a resident, or misappropriate a resident's property. The State must then maintain a record of all reported incidents.

We proposed that a facility may use a paid feeding assistant to feed residents who do not have a clinical condition that would require the training of a nurse or nurse aide. Selection of residents to be fed would be made by the professional nursing staff, using the comprehensive assessment. Nurses or nurse aides would continue to feed residents who require the assistance of staff with more specialized training, such as those residents with recurrent lung aspirations, difficulty swallowing, or those residents on feeding tubes or parenteral/IV feedings. Feeding assistants would work under the direct supervision of registered nurses (RN) or licensed practical nurses (LPN), who are in the unit or on the floor where the feeding assistance is furnished. In proposed § 483.75(e), we revised the definition of ''nurse aide'' to clarify that paid feeding assistants are not performing nursing or nursing-related tasks.

Feeding assistants could be paid by the facility or paid under an arrangement with another agency or organization (§ 488.301). Facilities would be able to use staff who are not health care personnel as feeding assistants if they successfully complete the training program. This might include the administrator, activity staff, clerical, laundry, housekeeping staff, or others who see residents on a daily basis. However, feeding assistants are intended to supplement certified nurse aides, not substitute for certified or licensed nursing staff.

We proposed that these requirements would not apply to volunteers and family members.

III. Analysis of and Responses to Public Comments

We received over 6,000 public comments on the proposed rule. About 99 percent of commenters were overwhelmingly supportive of the proposal, but raised a large number of issues and offered many suggestions for clarifications and revisions to the final regulation. Commenters supporting the proposal included for-profit and not-for-profit nursing homes, national and State nursing home associations, national and State health care associations, State health and human services agencies, United States Congresspersons, and private citizens. Many beneficiary advocates and employee unions opposed giving facilities the option to use paid feeding assistants. A summary of the major issues and our responses follow.

Facility Option To Use Feeding Assistants

Comment: One commenter recommended that we conduct a pilot study or do further research before finalizing the proposal because there is a lack of data that would support the proposal. Another commenter suggested that we implement the proposal, but reevaluate the policy in 3 years to see if the objective is being met.

Response: We believe that the experience of Wisconsin and North Dakota has provided a demonstration of the merits of the use of paid feeding assistants. Both States have reported that in facilities that use feeding assistants, the benefits to residents include fewer cases of unexplained weight loss and dehydration than in facilities that do not use feeding assistants, with no reported ill effects.

Comment: Some commenters believed that the proposal is illegal, that is, there is no basis in the law to support the use of paid feeding assistants.

Response: Our review of the law indicates that there is nothing that would prohibit the use of feeding assistants and we believe that we have the authority and discretion under the law to implement this practice. Although commenters have focused on the language of the statute, at sections 1819(b)(5)(F) and 1919(b)(5)(F) of the Act that requires persons engaged in nursing or nursing related care to be trained either as a nurse or nurse aide, we do not consider the kinds of tasks facilities may ask feeding assistants to

provide as either nursing or nursing related. While feeding has been part of the nurse aide training curriculum, that requirement was predicated on the nurse aide having to tend to persons with pronounced eating complications (such as swallowing disorders) for which specialized training is essential. What facilities would be free to do as a result of this rule, however, is to use persons who have had a lesser level of training to assist residents who have no feeding issues that require any specialized attention. Thus, we do not consider feeding assistants who may be used by facilities under this rule to be engaged in nursing or nursing related activities.

Comment: Several commenters cited the lack of Federal oversight built into the proposal.

Response: The survey process will provide the Federal oversight of facilities' use of feeding assistants, as it does for other participation requirements. During surveys of nursing homes, surveyors will observe the meal or snack service to note if any of the residents receiving feeding assistance are having trouble, such as coughing or choking. If this is observed, surveyors will investigate to determine if this is an unusual occurrence or a chronic problem and whether feeding assistants have successfully completed the 8-hour training course. Surveyors will also determine if the resident receiving the feeding assistance is one who has no complicated feeding problems. This will be done by a review of medical charts and discussion with the professional nursing staff. Similarly, surveyors will note concerns about supervision of paid feeding assistants and investigate how the facility provides supervision by interviewing staff during meal or snack times and drawing their own conclusions from observations. Deficiencies will be cited by surveyors when they identify problems. By retaining training and employment records of feeding assistants, a facility will help document its compliance with Federal requirements, and have a record that surveyors may review when they survey the facility.

Comment: Some commenters were convinced that the use of feeding assistants will not improve the quality of care and may, in fact, lower it. One commenter contended that Wisconsin's use of feeding assistants did not lead to a documented improvement in quality of care. Others commented that use of feeding assistants would disrupt the continuity of care and reduce quality by creating an assembly line atmosphere.

Response: We are not aware of any data that would suggest that there is an improvement in the quality of care when residents are helped to eat by feeding assistants, nor are we aware of any data that would suggest a decline in quality of care. We are relying on support for the use of paid feeding assistants that has been provided by the Wisconsin and North Dakota survey agencies. Neither agency has indicated that use of feeding assistants has resulted in diminished quality of care.

Comment: A few commenters recommended that we prohibit a facility from training feeding assistants when it has certain deficiencies, in the same way we currently prohibit a facility from training nurse aides. For example, commenters suggested that we prohibit facilities from training feeding assistants if the facility has (1) any deficiency at level F or above; (2) a deficiency at any level in the area of nutrition, staffing, and residents' rights; (3) imposed against it a per instance civil money penalty (CMP) of $5,000 or more, a per day CMP of $5,000 or more cumulatively, a State monitor, or temporary manager; (4) an approved nurse-staffing waiver.

Several consumer advocacy groups recommended that we limit the authority for a facility to use feeding assistants to facilities that are authorized to conduct nurse aide training programs. In other words, if a facility loses the right to train nurse aides, it should also lose the right to train feeding assistants. Many providers took the opposite position, that a facility that loses nurse aide training rights should retain the right to train feeding assistants.

Response: The prohibition to which commenters refer is a statutory requirement that causes a facility to lose the right to train nurse aides when the facility has certain deficiencies specified in the law. We disagree with commenters and believe that each State needs the flexibility to respond to specific situations and make its own decision whether or not to permit a facility to train and use feeding assistants.

Facilities that have an approved nurse-staffing waiver, which waives requirements in § 483.30 to have a RN on staff 8 hours per day, 7 days per week, are still required to have adequate numbers of LPNs on staff at all times. Thus, even if RNs are unavailable, the supervision requirement for feeding assistants would be met by having LPNs on duty.

Comment: Many commenters said that they did not want us to limit hours worked by feeding assistants to mealtimes and advocated permitting feeding assistants to work whenever needed by a facility. Some facilities thought that feeding assistants could be used full time to provide snacks and liquids to residents, particularly those who cannot leave their room. These commenters believed that this would be a good way to reduce the potential for dehydration since assistants would have time to deliver liquids, provide social stimulation, and encourage bedfast residents to drink more fluids.

Response: The text of the regulations does not limit working hours to mealtimes. According to § 483.35(h), facilities may use feeding assistants at any time that the supervision requirements are met.

Comment: Many providers and individuals expressed strong support for the use of existing staff as feeding assistants, after proper training. A large number of providers reported that they favor this because existing staff, such as clerical, dietary, and housekeeping staff, are already trained in facility policies, are usually well acquainted with residents, and have time available to devote to feeding residents.

A number of other commenters were opposed to using existing staff as feeding assistants, citing their full-time responsibilities and concern about added burden.

Response: The text of the proposed regulations permits any individual to act as a feeding assistant if he or she meets the training and supervision requirements (§ 483.35(h)). Each facility's administrator is responsible for allocating available staff to necessary tasks and we believe that it is reasonable to leave the decision to the administrator whether to use as feeding assistants staff who are not health care personnel.

Comment: Some commenters suggested requiring that facilities assign feeding assistants to certain residents to ensure continuity of care.

Response: We believe that this decision is best left to each facility and the supervisory nurses.

Comment: Consumer advocates were concerned that insufficiently trained feeding assistants would endanger residents. Other commenters were concerned that feeding assistants might make clinical judgments and take actions that are beyond their scope of training or be unable to handle emergency situations.

Response: The purpose of the training is to ensure that feeding assistants are properly prepared to feed residents and recognize emergency situations that need the immediate help of a supervisory nurse. We believe that a training program that meets the requirements listed in § 483.160 will

ensure that a feeding assistant receives proper training.

Comment: One commenter suggested that we consider expanding the role and training of feeding assistants so that they can eventually assist in feeding residents with complex feeding problems.

Response: Individuals who have complex feeding problems, such as the need for IV or parenteral feedings, swallowing problems, and those with recurrent lung aspirations, need the assistance of professional nurses or certified nurses aides who have been trained to work with residents who have these needs. We do not believe that it is appropriate for feeding assistants to feed any residents other than those who are low risk and whose eating problems are uncomplicated.

Comment: Two senators and one congressman wrote in support of the proposal, noting the success of one state that used feeding assistants and experienced reduced weight loss and dehydration among nursing home residents. These commenters also reported that the Board of Nursing of one state had defined feeding as a nursing task and was concerned that this might prevent the state from using feeding assistants. (In the proposal, we indicated that feeding assistants would not be performing nursing or nursing-related tasks.) Another commenter believed that feeding is a nursing-related service and should not be performed by an individual with minimal training.

Response: The definition of the term, ''nursing and nursing-related tasks,'' is frequently prescribed by State law and, therefore, we are declining to impose a Federal definition of this term on all States. We believe the matter should be left with the State in those situations in which State law or standards-setting organizations have established a definition that is more restrictive than the Federal definition permitting the use of feeding assistants. We suggest that the State investigate whether a revision to State law would resolve this issue.

Staffing Issues

Comment: One consumer advocacy group suggested that we require state survey agencies to use the investigative protocol for staffing from the *State Operations Manual* in all facilities that request to use or use feeding assistants. This protocol, used to identify problems that may be associated with insufficient nursing staff, would ensure that a facility has an appropriate number of RNs and LPNs to supervise feeding assistants.

Response: We believe that facilities that request to use or use feeding assistants should be surveyed in the same way as any other facility. Surveyors should use the investigative protocol for staffing only when systemic problems relate to insufficient nursing staff.

Comment: A consumer advocate asked that we require facilities to post information about the numbers of feeding assistants, in addition to the current requirement to post the number of licensed and unlicensed staff employed per shift. The commenter also suggested that we require that feeding assistants wear badges or name tags so that they will be clearly recognized by other staff.

Response: A provision in the Medicare, Medicaid & State Child Health Insurance Program (SCHIP) Benefits Improvement & Protection Act of 2000 (BIPA) requires facilities to post daily for each shift the current number of licensed and unlicensed nursing staff directly responsible for resident care in the facility. This provision is effective January 1, 2003. Because paid feeding assistants do not qualify as licensed or unlicensed nursing staff, facilities do not need to post the numbers of feeding assistants used by the facility. However, we will consider at a later date whether this might be useful and what additional burden it may impose on facilities.

With regard to name tags, we believe it is probably a good idea, but leave that decision to each facility and do not see the need for us to make this a requirement.

Use of Volunteers

Comment: Several commenters suggested that we require volunteers to complete the training requirements for feeding residents, pointing out that it is inconsistent not to do so.

Response: While we believe that it is a good idea for family members and volunteers to take the training, and we encourage it, we are not making this a requirement. Many volunteers in facilities are family members who are only there to feed a relative. Often, family members have been feeding the ailing resident for years, both at home and in the facility. We are leaving it to each facility to determine whether or not to require volunteers and family members to complete feeding assistance training. Ultimately, facilities are responsible for the care and safety of residents, even if the resident is fed by a relative or friend.

Payment Issues

Comment: Some providers were concerned about how they would be paid for the training and services of feeding assistants. A few commenters recommended that we allocate payment for feeding assistants to the nursing cost center.

Response: Skilled nursing facilities will not receive additional Medicare payment for the costs of using feeding assistants. Medicare payment for residents in skilled nursing facilities is made through a prospective payment system, which covers all costs (routine, ancillary, and capital) of covered skilled nursing facility services furnished to beneficiaries under Part A of the Medicare program. For Medicare payment, the term and concept, ''nursing cost center,'' is outdated, but still may be used in some State Medicaid programs. The Medicare SNF PPS per diem payment rate is based, in part, on levels of care and resources required and received by residents, established by the resident assessment instrument specified in § 483.20. The system does not require that tasks performed by a staff person fit within a direct care or indirect care category (such as a nursing cost center).

Medicaid payments for nursing facilities are established by each State. Therefore, it would be up to individual States to determine whether they would need to change their payment rates for those facilities that use feeding assistants and how the rates would be changed. However, because feeding assistants will likely be paid at a minimum wage, which is less than the wage paid to certified nurse aides, facilities participating in Medicare and Medicaid may incur less cost than if they had hired additional certified nurse aides to perform feeding and hydration duties.

Comment: One provider reported using workers who pass out trays, provide beverages and condiments, talk to and encourage residents, record food intake, and perform routine dining room tasks. The commenter asked if the facility would be able to continue to use these workers.

Response: A facility may continue to use workers who perform the dietary service functions described by the commenter. They need not be trained as feeding assistants if they do not feed residents. Facilities are required to employ sufficient support personnel to carry out the functions of the dietary service. If these workers successfully complete the feeding assistant training course, the facility may also use them to feed residents. However, as we indicated in the last response, the Medicare program pays skilled nursing facilities a prospectively determined per diem rate, which does not require that

tasks performed by personnel fit into a direct or indirect care category. For Medicaid payment, payment is determined by each Medicaid state agency.

Determining Which Residents Can Be Fed by Feeding Assistants

Comment: One state commented that it is cumbersome to rely on the comprehensive assessment to determine which residents may be safely fed by a feeding assistant. Instead, the decision should be left entirely up to the professional judgment of the licensed nurse. A consumer advocacy group also indicated that the comprehensive assessment/annual evaluation is not an effective tool for the assessment of residents to be fed because the information may not be current. Several organizations suggested that we emphasize the importance of the RN or LPN's professional judgment along with input from the interdisciplinary team, as reflected in the comprehensive assessment, when selecting residents for feeding assistance.

Response: We agree with commenters and are revising § 483.35(h)(1)(ii) to say that the decision about whether a resident is to be fed by a feeding assistant is based on the charge nurse's assessment and the resident's latest assessment and plan of care. We note that facilities that choose to use paid feeding assistants remain responsible for any adverse actions resulting from the use of these assistants, as with any other employee.

Comment: An organization representing licensed professionals suggested that the RN or LPN should consult with a speech-language pathologist when a resident is suspected to have, or is at risk for, swallowing difficulties.

Response: We have no objection to this and facilities may use this approach if they choose.

Comment: Several commenters indicated that the criteria for selecting residents to be fed is inadequate and suggested that we define the clinical conditions that would require feeding by an RN or LPN or nurse aide. Another commenter suggested that we prohibit feeding assistants from feeding residents with swallowing problems.

Response: We believe that the clinical decisions as to which residents may be fed by feeding assistants are best left to the professional judgment and experience of RNs and LPNs who work in the facility and have personal knowledge of a resident's day-to-day condition. If we were to define clinical conditions, we would only be substituting the judgment of professional nurses employed by the Federal government for the judgment of nurses working in facilities. We believe that professional nurses conclude that certain clinical conditions relating to eating and drinking would require the skills and knowledge of an RN or LPN. These conditions include, but are not limited to, recurrent lung aspirations, difficulty swallowing, and tube or parenteral/IV feedings.

Comment: One commenter suggested a number of more stringent requirements for facilities, including (1) obtaining informed consent from the resident or resident's representative that the resident agrees to be fed by a feeding assistant and accepts the risks and benefits; (2) an individualized feeding plan; and (3) a certification by a licensed nurse in a resident's medical record that the resident can be safely fed by a feeding assistant prior to each instance of feeding.

Response: We understand that the commenter intends the proposed provisions to be in the best interest of residents, but we believe that, for the most part, they are unduly burdensome for facilities to implement. To require consent before a resident can receive help from a feeding assistant implies that this is a high risk procedure, which we believe it is not. We believe that the Wisconsin and North Dakota experience indicates that it is safe to use well-trained feeding assistants who are properly supervised. It would be inconsistent to require residents to give informed consent for feeding assistance when they need not do so for any other services provided by a facility. Further, a feeding plan would very likely duplicate part of the care planning process. Consequently, we are not revising the rule to accommodate the commenter's suggestions.

Supervision

Comment: Commenters, concerned about lack of supervision, pointed out that the proposed requirement, in § 483.35(h)(2)(ii), that a nurse is in the unit or on the floor, exceeds the licensed nursing requirements in most states. Other commenters worried that the shortage and high turnover rates of licensed and unlicensed nursing staff could mean that fewer staff are familiar with residents and could result in inadequate monitoring.

Response: Facilities are required by § 483.30, Nursing services, to have sufficient qualified nursing staff available on a daily basis to meet residents' needs for nursing care. The requirement in § 483.30, Nursing services, is that, unless waived, a facility must have a RN on duty 8 consecutive hours per day, 7 days a week. A facility must also have a sufficient number of licensed nurses and other nursing personnel on a 24-hour basis to provide nursing and related services to residents. The proposed requirement that a feeding assistant work under the direct supervision of a RN or LPN builds on the requirement that sufficient licensed nursing staff are on duty 24 hours a day. We believe that, if a facility chooses to use feeding assistants, it is the facility's responsibility, and in its best interest, to ensure that adequate supervisory nursing staff is available.

However, we recognize that the supervision requirement is unclear and subject to a variety of interpretations. Therefore, we are revising § 483.35(h)(2) by removing the word, ''direct'' from the phrase, ''direct supervision,'' because it may unintentionally imply visual contact between a feeding assistant and a supervisory nurse. This is not possible in most facilities, especially if assistants are feeding residents in their rooms. Next, we are removing the requirement that a nurse be in the unit or on the floor where the feeding assistance is furnished and immediately available to give help. As commenters noted, this sentence is unclear. While we are not prescribing the precise means by which facility RNs or LPNs assert their supervisory responsibilities, we will expect that facilities do so in a way that avoids negative outcomes for their residents. Additionally, we are requiring that a feeding assistant call a supervisory nurse on the resident call system when there is an emergency or a need for help. All facilities are currently required to have a resident call system.

Comment: Consumer advocates expressed concern about a potential lack of supervision and suggested that all residents who are fed by feeding assistants be fed in the dining room or other congregate area to ensure that a licensed nurse is physically present. Other commenters supported allowing feeding assistants to feed residents in their rooms, citing the fact that many of the most frail residents do not go to the dining room and are least likely to get adequate assistance with eating. Numerous commenters cited examples of bedfast residents, unable to feed themselves or reach the food, receiving no help at mealtime, after which the tray is removed, untouched by the resident.

Response: We share commenters' concerns about adequate supervision of feeding assistants to ensure the safety of residents. We are equally concerned, however, that those residents who are

unable or unwilling to go to a congregate dining area receive needed feeding assistance in their rooms. We are confident that the nurse in charge, using his or her professional judgment in assessing residents who are appropriate for feeding assistance, will be able to select residents who can safely be fed in their own rooms.

Comment: An organization representing nursing home employees noted that nursing staff is already overworked and supervising feeding assistants would only add to the burden. Another commenter indicated that the proposed supervision requirement would further burden RNs and LPNs because they would have to stay in the dining room during mealtimes and this would limit their availability elsewhere in the facility.

Response: Adequate supervisory staff is just one factor that a facility needs to consider when deciding whether or not to use feeding assistants. If a facility chooses to use paid feeding assistants, it would be the facility's responsibility to ensure that it has sufficient RNs and LPNs available to adequately supervise feeding assistants without adding undue burden on the staff. When using feeding assistants, there will be a need for a facility to balance the increase in staff available to meet resident needs with the increased need to supervise these assistants.

Training

State-Approved Training Course

Comment: Several providers asked whether facilities would be able to hire paid feeding assistants if the State does not approve a training program for feeding assistants. Many providers supported giving facilities maximum flexibility to implement the proposal without lengthy state approval requirements. One commenter suggested that we require all states to mandate feeding assistant programs in all facilities.

Other commenters believed that, before facilities may opt to use feeding assistants, States should be able to decide whether implementing feeding assistant programs is in the best interest of the State or consistent with State law.

Several providers, provider organizations, and States asked that we remove the requirement that a training course for feeding assistants be State approved, citing potential burden on States, cost, and delays in implementing feeding programs. One State with a large number of facilities and a shortage of resources was concerned about the potential burden of approving a large number of feeding programs. Commenters, instead, suggested that we require that an individual complete a training course that meets the requirements of § 483.160. In this case, the facility would maintain documentation of compliance with the requirements and surveyors would review the training records at annual surveys.

Many states and providers asked for clarification on our expectations in terms of state approval. They wondered whether other entities, such as community colleges, would be permitted to offer the training. One commenter noted that travel to community colleges and cost would discourage individuals from taking the training. There was also a question about the frequency with which a state would need to review or reapprove a feeding assistant program. Another commenter suggested that we offer more specific guidance to states to assist them in establishing criteria for training programs and others suggested using established models from Wisconsin and North Dakota.

Response: We have chosen to retain the requirement that States approve training programs for feeding assistants. We believe that this will give States the necessary control and flexibility to structure approval processes for training programs to fit the needs of each State. States that have large numbers of facilities and resources that are stretched to the limit may want to minimize any burden associated with State approval of training programs, while States with fewer facilities may structure approval in a very different way.

However, States also have the flexibility not to implement a program for approval of feeding assistant training programs. If a State does not implement an approval program, the result is that facilities in that State will not be able to hire any paid feeding assistants.

Training Content

Comment: We received a variety of comments on training, including requests for additional requirements, removal of requirements, and clarifying changes. Many commenters asked that we provide more specificity on training requirements and establish a minimum number of hours of training. Suggestions for hours of training ranged from 5 to 75.

Response: We believe that being overly prescriptive on the content of training is unnecessary, would reduce flexibility to offer these training programs, and would unnecessarily limit the ability of States and providers to develop these programs within the scope of their considerable knowledge. However, to ensure that training is not conducted in a superficial manner, we are revising § 483.160(a) to require that a training course for feeding assistants include, at a minimum, 8 hours of training.

Comment: A few commenters suggested that we specify in the text of the regulation that a feeding assistant must ''successfully'' complete the entire training course before he or she is qualified to work with residents in the facility.

Response: We agree with the commenters that successful completion of the training course is essential and are revising § 483.35(h)(2)(i) by adding the word ''successful.'' We believe that it is reasonable to expect that a feeding assistant will successfully complete the training course before working directly with residents. This is a basic safety precaution to ensure that residents are protected. After completion of training, a facility may want to slowly ease a feeding assistant into the work by feeding a resident who needs minimal assistance, as North Dakota does.

Comment: Many commenters advocated requiring a competency test before feeding assistants are permitted to work with residents.

Response: We are not including a requirement for a competency test in the final rule. We believe that the instructor or supervisory nurse will be able to assess the competency of trained feeding assistants.

Comment: Several commenters objected to the inclusion of the Heimlich Maneuver in the training course and its use by feeding assistants. They were concerned that its use by a robust feeding assistant on a frail resident might result in rib fractures or other injuries. Commenters emphasized that only nursing staff should determine the need for, and administer, the Heimlich Maneuver. Instead, they suggested that the training course emphasize the need for feeding assistants to recognize symptoms that should be immediately reported to licensed supervisory staff for further action.

Response: The Heimlich Maneuver is an emergency procedure that is taught to the public, as well as medical personnel. It seems reasonable to retain this training requirement in view of the fact that nurse aides are trained to use this procedure and they may also be strong individuals. Proper training is essential and feeding assistants will receive the same training on the Heimlich Maneuver as nurse aides. Also, experienced RNs tell us that training in handling emergencies will

emphasize the need for a feeding assistant to call for help immediately, and then, if necessary, begin a procedure like the Heimlich.

Comment: One commenter suggested that, if a facility uses a feeding assistant under an arrangement with another organization, the facility must verify that the feeding assistant has successfully completed the training.

Response: Section 483.35(h)(2) already provides for this. It says that, if a facility uses a paid feeding assistant, the facility must ensure that the individual has completed a State-approved training course. The burden of proof is on the facility to ensure that any feeding assistant it uses is properly trained.

Comment: Commenters suggested a number of additions to the general training requirements. One suggestion was to require that training programs explicitly include feeding problems of the cognitively impaired, since 60–70 percent of nursing home residents are cognitively impaired. Other suggestions included training in dementia, food and drug interactions, diet consistencies, how much and how to feed, resident preferences, difficulty swallowing, and emphasis on performing only feeding tasks for which training has been provided. A consistent concern of commenters was a need for a training emphasis on recognition and prevention of emergency situations associated with feeding, such as dysfunctional swallowing, tracheal aspiration, esophageal obstruction, and other potentially severe emergency situations.

Response: It is important to note that the training course requirements proposed in § 483.160 are minimum requirements. States and facilities are free to add to those requirements. However, many of the training additions suggested by commenters appear to be more useful in the training of nurse aides than feeding assistants, who will feed residents without any significant eating problems.

Comment: Several commenters suggested that we address payment for training in the same way that we do in the regulations for nurse aides. One commenter asked that we prohibit facilities from charging potential feeding assistants for training. Another asked if a facility may require that a trained feeding assistant repay the facility for training if he or she leaves? A commenter asked if a facility can require that a trained feeding assistant work for a set period of time.

Response: Judging from provider comments received, there will be a strong demand for feeding assistants and it is unlikely that facilities will want to charge for training. Generally, these positions will be part time and will not require extensive training that would be costly for the facility. We think it is unnecessary to amend the regulations to provide for payment provisions similar to those for nurse aides. With regard to a facility entering into a contract with a feeding assistant that would require that individual to work for a certain period of time, there is nothing in our regulations that would prohibit this practice. This is strictly between the facility and the feeding assistant.

Qualifications of Instructors

Comment: Many individual commenters and professional organizations asked that we establish standards or qualifications for instructors of the training program. Commenters suggested numerous licensed or certified health care professionals who could conduct the training, including RNs, registered dietitians, licensed physical therapists, licensed speech therapists, and occupational therapists. Dietitians argued that they have the expertise in food and nutrition issues in long-term care settings, are trained to teach self-help feeding devices, and basic restorative feeding services, citing established manuals and materials that would support this practice. Occupational therapists argued that they are trained to match an analysis of disabilities with effective interventions, resources and adaptations.

Several commenters strongly recommended that we prohibit feeding assistants from teaching each other on-the-job.

Response: It is apparent that a number of options are available in terms of the variety of licensed or certified health care professionals that may be qualified to conduct training for feeding assistants. Some, RNs and LPNs, are employed full time in facilities and would be available without additional cost to conduct the training. Dietitians may be employed by a facility full time, part time, or on a consultant basis. Other health care professionals may be available at additional cost; however we believe that it would be inappropriate to permit a feeding assistant to train another. Consistent with the flexibility for States to develop a State-approved training program, we are deferring to States the decision as to which individuals would be qualified to teach the feeding assistant training.

Maintenance of Records

Comment: Several commenters pointed out that there is no requirement for states to maintain a formal registry of feeding assistants or to check with other states for background information. One commenter suggested that states report information on feeding assistants to the nurse aide registry and provide this information to facilities for hiring purposes. Others suggested that we require facilities to check with the nurse aide registry before employing individuals as feeding assistants in case the individual had worked as a nurse aide previously.

Response: We have decided to include only nurse aides in the nurse aide registry, largely because the law is so specific about the requirements. Also, we believe it is not necessary to further burden States by requiring them to establish and maintain a separate registry for feeding assistants. As we explain later in the preamble, states are already required by § 488.335 to review and investigate all allegations of abuse, neglect, and misappropriation of resident property. This information can be accessed by any hiring facility. Facilities need to screen feeding assistants, as any other employee, to try to ensure that individuals have no history that would preclude their interaction with frail elderly residents.

Comment: Several commenters reported that there is no provision for feeding assistants trained in one facility, city, or state to carry that training forward so that it does not have to be repeated. There is no requirement for a facility to request a copy of an individual's training record before he or she is hired as a feeding assistant. A commenter suggested that we establish a requirement for states to have reciprocity agreements within each state or between states.

Response: It is not our intent that individuals repeat training when moving to another facility. However, we believe that it is unnecessary to establish extensive regulatory provisions for requesting records or for state reciprocity agreements in this case. As with any other job applicant, a feeding assistant should indicate where he or she was last employed and a hiring facility may contact the former employer to verify employment and training. States are currently required to review allegations of abuse, neglect, or misappropriation of resident property. A hiring facility should be able to contact the state for that information.

Reporting Abuse, Neglect, and Misappropriation of Residents' Property

Comment: Commenters had a number of suggestions concerning proposed § 483.160(c), which requires a facility to report to the state all incidents of a paid

feeding assistant who has been found to neglect or abuse a resident, or misappropriate a resident's property. That section also requires a state to maintain a record of all reported incidents. One state reported that it already has a requirement for criminal background checks and a law requiring that facilities report allegations of abuse and neglect. Other commenters suggested language changes to the text. One commenter noted that § 483.160(c) is inconsistent with § 488.335, which requires a state to review all allegations of resident neglect, abuse, and misappropriation of property, and follow procedures in § 488.332. Section 488.332 requires a state to establish procedures to investigate complaints of participation requirements.

Response: We agree with the commenter regarding requirements in proposed § 483.160(c). Paragraph (c) is unnecessary because it repeats certain provisions of existing § 488.335. Since § 488.335 already establishes state requirements for review of allegations of neglect, abuse, misappropriation of property, and procedures for investigation of complaints and hearings, we are removing proposed paragraph (c) in § 483.160.

Definition of Paid Feeding Assistant

Comment: Many commenters objected to the term, feeding assistant, saying that it has a pejorative connotation and it lacks sensitivity to the elderly. Others thought that the term failed to include the importance of fluid intake. Commenters suggested a variety of alternatives, including the following: meal assistant; food and hydration aide or assistant; nourishment aide, nutrition assistant, nutritional aide, nutrition-hydration assistant; dining assistant; and resident assistant.

Response: The commenters make a good point, which we had not recognized when drafting the proposal. However, the term, feeding assistant, was widely used by states and organizations before our proposal. Rather than change the term in the regulations, we suggest that facilities and states use whatever term they prefer.

IV. Provisions of the Final Regulations

For the most part, this final rule incorporates the provisions of the proposed rule. The following provisions of this final rule differ from the proposed rule:

- We are reorganizing and revising § 483.35(h) so that paragraph (h)(1) applies to State approval of training courses for feeding assistants. We are adding the requirement that a feeding assistant must successfully complete a State-approved training course, and do so before feeding residents.
- Also, in revised § 483.35(h)(1), we are clarifying that a facility may use a paid feeding assistant if it is consistent with State law.
- In revised § 483.35(h)(2), we are revising the supervision requirement to remove the word, ''direct,'' from the phrase, ''direct supervision.''
- Also, in revised § 483.35(h)(2), we are removing the requirement that a supervisory nurse be in the unit or on the floor where the feeding assistance is furnished and is immediately available to give help, if necessary. In place of that sentence, we are adding the requirement that a feeding assistant call a supervisory nurse for help during an emergency on the resident call system.
- In revised § 483.35(h), we are adding a new paragraph (3) concerning resident selection criteria to replace proposed § 483.35(h)(1)(ii). In new paragraph (3), we are replacing the term, ''clinical condition'' with the phrase, ''complicated feeding problem.''
- In § 483.35, we also specify that a complicated feeding problem includes, but is not limited to, difficulty swallowing, recurrent lung aspirations, and tube or parenteral/IV feedings.
- Also, in § 483.35, we provide that a facility must base resident selection on the charge nurse's assessment and the resident's latest assessment and plan of care.
- In § 483.160(a), we are adding a requirement that the State-approved training course include a minimum of 8 hours of training covering the topics listed in § 483.160(a).
- In § 483.160(c), we are removing the requirement that a facility report to the State all incidents of a paid feeding assistant who has been found to neglect or abuse a resident, or misappropriate a resident's property, and that a State must maintain a record of all reported incidents. This paragraph unnecessarily duplicates existing requirements in § 488.335, Action on complaints of resident neglect and abuse, and misappropriation of resident property.

V. 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 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 OMB should approve an information collection, section 3506(c)(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.

Nursing homes in two States currently use feeding assistants and eight other States have expressed an interest in implementing this policy. While public comments from nursing homes and provider organizations indicated strong support for the use of feeding assistants, only 13 States responded to the proposal. Some States indicated interest and others had concerns about the cost of implementation and other issues, so we do not now have a better idea of how many States will choose to approve the use of feeding assistants in nursing homes. In addition, it remains a facility option, so we still do not know how many facilities in which States will choose this option, nor do we know how many feeding assistants would be used by each facility. There are approximately 17,000 nursing homes in the nation, and they are not evenly distributed within States. Wisconsin reported that about 25 percent of nursing homes in the State used feeding assistants. On a nationwide basis, we believe that it is reasonable to project that 20 percent of facilities will use feeding assistants. We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements:

Section 483.160(b)

1. Requirement

A facility must maintain a record of all individuals, used by the facility as feeding assistants, who have successfully completed the training course for paid feeding assistants.

2. Burden

We estimate that 20 percent of nursing homes may implement this policy (20 percent of 17,000 = 3,400 facilities/respondents). If we assume that each facility will hire two feeding assistants, this results in a total of 6,800 feeding assistants. Depending on the method chosen by a facility to collect this information, we believe that each facility (respondent) would spend no more than 30 minutes per month (6 hours per year) entering feeding assistant information into its record-

keeping system. Some months, facilities may have no information to add. With 3,400 facilities at 6 hours/year, the total would be 20,400 hours for facilities. Using a clerical wage cost of $10 per hour, the total facility burden is estimated to be $204,000.

We are submitting a copy of regulation § 483.160 to OMB for its review of the information collection requirements. The revision is not effective until OMB has approved it.

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

Centers for Medicare & Medicaid Services, Office of Information Services, Information Technology Investment Management Group, Attn.: Julie Brown, Room C5–16–03, 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: Brenda Aguilar, CMS Desk Officer.

Comments submitted to OMB may also be emailed to the following address: email: *baguilar@omb.eop.gov;* or faxed to OMB at (202) 395–6974.

VI. Regulatory Impact Statement

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 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). This rule is not a major rule. The costs of using feeding assistants will be covered by existing Medicare payment and, most likely Medicaid payment, depending on how a State establishes payment rates. Skilled nursing facilities receive an all-inclusive per diem Medicare payment rate for each resident's care. This includes all costs (routine, ancillary, and capital) of covered skilled nursing facility services furnished to beneficiaries under Part A of the Medicare program. Skilled nursing facilities will not receive additional Medicare payment for the costs of using feeding assistants.

Medicaid payments for nursing facilities are established by each State. Therefore, it would be up to individual States to determine whether they would need to change their payment rates for those facilities that use feeding assistants and how the rates would be changed. However, because feeding assistants will likely be paid at a minimum wage, which is less than the wage paid to certified nurse aides, facilities participating in Medicare and Medicaid that use feeding assistants may incur less cost than if they had hired additional certified nurse aides to perform feeding and hydration duties.

State costs associated with feeding assistant training programs are considered administrative expenses and are funded under Medicaid with matching funds at 50 percent Federal financial participation. Any information we have on potential State costs of implementing feeding assistant programs comes from States that have used such programs in the past. One State, Wisconsin, has a well-structured program and has experienced relatively minimal costs. One registered nurse spends approximately 10 percent of her time reviewing and approving facility feeding assistant training programs. This represents 10 percent of a full-time equivalent position (FTE), which is reported by Wisconsin to be a cost of about $7,000 per year. At a time when the use of feeding assistants was highest, a quarter of Wisconsin's 420 nursing homes, or 100 to 110 facilities, used feeding assistants. The number of feeding assistants used by each facility varies according to the size of the home, with the maximum number estimated to be 5 for a large, 200- to 250-bed home. Feeding assistants are typically paid at the same minimum wage. The number of hours each feeding assistant works at a facility is also variable and different for each worker and facility. Further, some facilities use only existing staff as trained feeding assistants. Because of the number of hours worked by each feeding assistant is variable, we do not have an exact estimate of the total cost to Wisconsin for using feeding assistants. However, this summary of Wisconsin's program may be helpful to other States, which are interested in establishing feeding assistant programs.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 to $29 million in any 1 year. For purposes of the RFA, all long-term care facilities are considered to be small entities. Individuals and States are not included in the definition of a small entity. The Small Business Administration considers 62 percent of long term care facilities to meet their definition of small entity (those facilities with total revenues of $11.5 million or less in any 1 year. We have determined that this rule will affect these entities, but, in general, we expect any cost to be covered by Medicare and Medicaid program payments.

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 Metropolitan Statistical Area and has fewer than 100 beds. This final rule does not affect small rural hospitals.

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined that this rule will not have a significant economic impact on a substantial number of small entities or 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 that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This final rule will not have a cost greater than $110 million on the governments mentioned or on the private sector. In general, we believe that existing Medicare and Medicaid payments will cover the facility costs of using feeding assistants. Costs associated with surveys of long term care facilities are Federally funded, as are costs of State approval of training programs.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We believe that this rule contributes to State flexibility by giving States the option to allow the use of feeding

assistants, control over how to structure the process of the approval of facility feeding assistant programs, and over elements of training, including instructor qualifications. In this way, States can establish policies that fit their unique circumstances. We believe that this rule will not have a substantial effect on State or local governments.

B. Anticipated Effects

These provisions will affect long term care facilities. We expect the provisions to be a substantial benefit both to facilities that are short-staffed and to residents who need help with eating and drinking. By using feeding assistants to help residents with eating and drinking, facilities can use trained, certified nurse aides to perform other, more complex resident care tasks.

Based on the large number of comments we received from nursing homes in a variety of States, we now believe that there is widespread support for the proposal and widespread intent to implement the provisions. However, because this is an optional provision, and some States may have legal barriers to implementation, we do not know how many States or facilities may implement these provisions, or how many feeding assistants will be used by facilities. Based on public comments, we anticipate that some facilities may hire no additional staff as feeding assistants, opting instead to use existing staff whose primary function is not direct care of residents, such as administrative or activities staff. We believe that feeding assistant training most likely will be conducted by existing facility staff and that there will be some nominal training costs to the facility since training requires time away from other duties that other staff may have to perform.

State-Approved Training Programs

We require that a feeding assistant successfully complete an 8-hour State-approved training course, which meets the Federal requirements in § 483.160(a). We have established no requirements on how States are to approve these programs, thereby giving each State the flexibility to decide what method makes the most sense in terms of use of its resources. There are several ways in which States may approach approval of training programs. States might choose to develop a model training program that complies with Federal requirements and require that any facility that trains and uses feeding assistants use that specific program. One model might be based on an existing training program already established, such as those conducted in Wisconsin or North Dakota. A State might choose to do a paper review of each facility's training program, or the State might insist on a site visit to review a facility's program. Lastly, a State might initially deem each facility's training program approved and then review the program when the facility is next surveyed. For some of these options, a State may need additional staff hours to review and approve training programs. However, States already review and approve training programs for nurse aides, so there is an existing administrative structure in place. There is the potential for increased State costs associated with review and approval of facility feeding assistant programs. However, any cost will depend on the approval method that is chosen by each State.

1. Effects on the Medicare and Medicaid programs.

There are approximately 17,000 facilities nationally. Long term care facilities that participate in the Medicare and Medicaid programs must provide the necessary care and services to residents so that they attain or maintain the highest practicable physical, mental, and psychosocial well being. To do this, facilities must employ sufficient staff on a 24-hour basis, including nursing staff, administrative, medically-related social services, dietary, housekeeping, and maintenance staff.

The Medicare program pays for skilled nursing facility services to eligible beneficiaries through a prospective payment system that covers all costs of covered services furnished to residents on a per diem basis. This Medicare SNF PPS per diem payment rate is based, in part, on levels of care and resources required and received by residents. The payment rate covers all care required and received by a resident and does not require that tasks performed by a staff person fit within a direct or indirect care category. Therefore, the Medicare program would not pay a skilled nursing facility any additional funds if the facility chooses to use feeding assistants.

Medicaid payments for nursing facilities are established by each State. Therefore, it would be up to individual States to determine whether they would need to change their payment rates for those facilities that use feeding assistants and how the rates would be changed.

C. Alternatives Considered

There has been a continuing shortage of certified nurse aides in recent years, along with a shortage of RNs and LPNs willing to work in nursing homes. Certified nurse aides perform the majority of resident care in a long term care facility and are the lowest paid workers, while RNs and LPNs receive higher wages commensurate with their advanced training, experience, and supervisory responsibilities.

One alterative to the use of paid feeding assistants is to broaden the hours during which meals are served so that everyone is not fed at the same time within a one-hour mealtime. Expanded meal service, covering perhaps a 3-hour mealtime, or a restaurant model, where meals are available most of the time, would allow existing staff more time to help feed residents. However, this option already exists in regulations, and other than a few innovative facilities, nursing homes have chosen not to use this method. The current preference of most nursing homes is for an institutional approach in which meals are served to all residents early morning, noon, and evening at fixed hours. As a result, the nursing home industry prefers the use of feeding assistants rather than an expanded meal service. The other alternative is not to publish a regulation on the use of feeding assistants and, instead, make greater use of volunteers to assist with feeding. The use of volunteers to assist with feeding assistance is permitted in the current regulations. However, it is questionable whether facilities could find sufficient numbers of volunteers to meet their needs.

D. Conclusion

We believe that both residents and providers will benefit from these provisions. Residents will receive more assistance with eating and drinking, both at meals and at snack time. Facilities will be able to use existing staff to assist at mealtimes and hire additional staff to meet the needs of residents, freeing certified nurse aides to perform more complex tasks that require their training.

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

List of Subjects

42 CFR Part 483

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

42 CFR Part 488

Health facilities, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, CMS is amending 42 CFR chapter IV as set forth below:
■ A. Part 483 is amended as follows:

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

Subpart B—Requirements for 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. In § 483.35, the introductory text is republished, paragraph (h) is redesignated as paragraph (i), and a new paragraph (h) is added to read as follows:

§ 483.35 Dietary services.

The facility must provide each resident with a nourishing, palatable, well-balanced diet that meets the daily nutritional and special dietary needs of each resident.

* * * * *

(h) *Paid feeding assistants*—(1) *State-approved training course.* A facility may use a paid feeding assistant, as defined in § 488.301 of this chapter, if—

(i) The feeding assistant has successfully completed a State-approved training course that meets the requirements of § 483.160 before feeding residents; and

(ii) The use of feeding assistants is consistent with State law.

(2) *Supervision.* (i) A feeding assistant must work under the supervision of a registered nurse (RN) or licensed practical nurse (LPN).

(ii) In an emergency, a feeding assistant must call a supervisory nurse for help on the resident call system.

(3) *Resident selection criteria.*

(i) A facility must ensure that a feeding assistant feeds only residents who have no complicated feeding problems.

(ii) Complicated feeding problems include, but are not limited to, difficulty swallowing, recurrent lung aspirations, and tube or parenteral/IV feedings.

(iii) The facility must base resident selection on the charge nurse's assessment and the resident's latest assessment and plan of care.

* * * * *

§ 483.7 [Amended]

■ 3. Section 483.7 is amended as follows:
■ a. In paragraph (e)(1), the definition of ''Nurse aide'' is amended by adding a sentence to the end of the definition;
■ b. A new paragraph (q) is added.

The additions read as follows:

§ 483.75 Administration.

* * * * *

(e) * * * (1) * * *

(1) * * * Nurse aides do not include those individuals who furnish services to residents only as paid feeding assistants as defined in § 488.301 of this chapter.

* * * * *

(q) *Required training of feeding assistants.* A facility must not use any individual working in the facility as a paid feeding assistant unless that individual has successfully completed a State-approved training program for feeding assistants, as specified in § 483.160 of this part.

Subpart D—Requirements That Must Be Met by States and State Agencies: Nurse Aide Training and Competency Evaluation; and Paid Feeding Assistants

■ 4. The heading of subpart D is revised to read as set forth above.

■ 5. A new § 483.160 is added to read as follows:

§ 483.160 Requirements for training of paid feeding assistants.

(a) Minimum training course contents. A State-approved training course for paid feeding assistants must include, at a minimum, 8 hours of training in the following:

(1) Feeding techniques.

(2) Assistance with feeding and hydration.

(3) Communication and interpersonal skills.

(4) Appropriate responses to resident behavior.

(5) Safety and emergency procedures, including the Heimlich maneuver.

(6) Infection control.

(7) Resident rights.

(8) Recognizing changes in residents that are inconsistent with their normal behavior and the importance of reporting those changes to the supervisory nurse.

(b) Maintenance of records. A facility must maintain a record of all individuals, used by the facility as feeding assistants, who have successfully completed the training course for paid feeding assistants.

■ B. Part 488, subpart E is amended as follows:

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

Subpart E—Survey and Certification of Long Term Care Facilities

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

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1895hh).

■ 2. Section 488.301 is amended by adding a new definition of ''Paid feeding assistant'' in alphabetical order to read as follows:

§ 488.301 Definitions.

As used in this subpart—

* * * * *

Paid feeding assistant means an individual who meets the requirements specified in § 483.35(h)(2) of this chapter and who is paid to feed residents by a facility, or who is used under an arrangement with another agency or organization.

* * * * *

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

Dated: May 22, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Approved: June 24, 2003.

Tommy G. Thompson,

Secretary.

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LEGAL SERVICES CORPORATION

45 CFR Part 1626

Alien Eligiblity for Representation by LSC Programs

AGENCY: Legal Services Corporation.

ACTION: Final rule.

SUMMARY: The Legal Services Corporation (''Corporation'') is revising the appendix to its regulations on restrictions on legal assistance to aliens. This appendix sets forth a listing of documents upon which recipients may rely to verify the eligibility of non-U.S. citizens' applicants for legal assistance from LSC-funded programs.

EFFECTIVE DATE: This rule is effective as of September 26, 2003.

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SUPPLEMENTARY INFORMATION: Recipients of Legal Services Corporation (''Corporation'') funds are permitted by law to provide legal assistance only to U.S. citizens and certain legal aliens. Recipients are required to verify the