

CMS-3140-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 483

CMS-3140-P

RIN 0938-AP32

**Medicare and Medicaid Programs; Requirements for Long Term Care Facilities;
Hospice Services**

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the requirements that an institution would have to meet in order to qualify to participate as a skilled nursing facility (SNF) in the Medicare program, or as a nursing facility (NF) in the Medicaid program. We are proposing these requirements to ensure that long-term care (LTC) facilities (that is, SNFs and NFs) that chose to arrange for the provision of hospice care through an agreement with one or more Medicare-certified hospice providers would have in place a written agreement with the hospice that specified the roles and responsibilities of each entity.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on **[OFR--insert date 60 days after date of publication in the Federal Register]**.

ADDRESSES: In commenting, please refer to file code CMS-3140-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" and enter the file code to find the document accepting comments.

2. By regular mail. You may mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-3140-P,
P.O. Box 8010,
Baltimore, MD 21244-8010.

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

3. By express or overnight mail. You may send written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-3140-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

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

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

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

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

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

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

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

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

FOR FURTHER INFORMATION CONTACT:

Trish Brooks, (410) 786-4561.

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Jeannie Miller, (410) 786-3164.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

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

I. Background

According to CMS data, at any point in time, approximately 1.4 million elderly and disabled nursing home residents are receiving care in nearly 16,000 Medicare- and Medicaid-certified Long-Term Care (LTC) facilities in the United States. More than 20 percent of older Americans die in nursing homes. (Johnson, Sandra H., Hastings Center Report, Making

room for dying: end of life care in nursing homes; November/December 2005, Special Report 35 (6), S37-S41.) Therefore, providing care at the end of life, particularly palliative care, is an important part of nursing home care.

Palliative care means patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care in an LTC facility involves addressing physical, intellectual, emotional, social, and spiritual needs, as well as facilitating resident autonomy, access to information, and choice throughout the continuum of illness. Palliative care independent of the hospice benefit may also be provided by LTC facilities, which may eliminate the need for hospice services for their residents.

Hospice care is provided for terminally ill individuals with a prognosis of 6 months or less if their terminal illness runs its normal course. These patients have elected to forgo curative care and wish to remain in their place of residence. A Medicare-certified hospice provides services in family homes, LTC facilities, and any other dwelling that individuals call “home.” Hospice care may also be provided while individuals are hospitalized.

According to a March 2000 Office of the Assistant Secretary for Planning and Evaluation’s (ASPE) study, entitled “Use of Medicare’s Hospice Benefit by Nursing Facility Residents,” nursing facilities served approximately 35 percent of all hospice beneficiaries in some markets. The study concluded, “hospice in nursing homes is a very prevalent phenomenon,” but added that “Guidelines are . . . needed to clarify the need for nursing facilities to provide palliative care and the roles and responsibilities of hospices and nursing facilities when treating a hospice patient. Minimal contract provisions affecting the two types of providers when treating residents enrolled in hospice are needed as well.”

(<http://aspe.hhs.gov/daltcp/reports/2000/samhbes.htm>.)

Under current regulations, an LTC facility may choose to have a written agreement with one or more hospice providers to provide hospice care to a Medicare eligible resident who wishes to elect the hospice benefit. However, if the facility chooses not to contract with a Medicare-certified hospice to provide hospice services for the resident who wishes to elect the benefit, the LTC facility is responsible for assisting the resident in transferring to a facility that will arrange for the provision of such services, as requested by the resident. (See 42 CFR §483.12(a)(2)(i), Transfer and discharge requirements.)

Hospice care for residents who choose to live in various types of facilities has come under scrutiny as a result of a variety of findings, including Operation Restore Trust (ORT) activities, Office of Inspector General (OIG) reports from 1997, (U.S. D.H.H.S. OIG, “Hospice and Nursing Home Contractual Relationships,” Nov. 1997, OEI-05-95-00251, <http://oig.hhs.gov/oei/reports/oei-05-95-00251.pdf>) and 1998 (OIG Special Fraud Alert, “Fraud and Abuse, Nursing Home Arrangements with Hospices,” Mar. 1998 <http://oig.hhs.gov/fraud/docs/alertsandbulletins/hospice.pdf>), and a 2000 report from the Department’s Assistant Secretary for Planning and Evaluation (ASPE) Office of Disability, Aging and Long-Term Care Policy and the Urban Institute; “Synthesis and Analysis of Medicare Hospice Benefit Executive Summary and Recommendations.” (Harvell, J.; Jackson, B.; Gage, B.; Miller, S.; and Mor, V., Mar. 2000, <http://aspe.hhs.gov/daltcp/reports/2000/samhbes.htm>). In addition, based on feedback to CMS from state surveyors, there is a lack of coordination between LTC facilities and Medicare-certified hospice providers.

We believe there is a lack of clear regulatory direction regarding the responsibilities of providers in caring for LTC facility residents who receive hospice care from a Medicare-

certified hospice provider, which could result in duplicative or missing services. We believe this problem would be remedied by a regulatory requirement for a written agreement between the two types of entities when they are both involved in the care of a Medicare beneficiary. A written agreement would help ensure that required services are provided to beneficiaries and protect beneficiary health and safety, which could be endangered by a lack of coordination between hospice and LTC providers. Such an agreement ensures that care is coordinated by specifying what services each provider will provide. For instance, an LTC facility is considered a resident's home. An agreement between the providers would specify that the LTC facility must furnish room and board and meet personal care and nursing needs, while the hospice must provide services that are necessary for the care of the resident's terminal illness, such as counseling and palliation of pain.

A. Statutory authority

1. Overview

Sections 1819(b)(4)(A)(i) and 1919(b)(4)(A)(i) of the Social Security Act (the Act) state that, to the extent needed to fulfill all plans of care described in sections 1819(b)(2) and 1919(b)(2) of the Act, a skilled nursing facility or nursing facility must provide (or arrange for the provision of) nursing and related services and specialized rehabilitative services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident. The Omnibus Budget Reconciliation Act (OBRA) of 1986 permitted States to add a hospice benefit to their State Medicaid plans. The original legislation (OBRA '86), adding the optional hospice benefit, specified, "hospice care may be provided to an individual while such individual is a resident of a skilled nursing facility or intermediate care facility" (P.L. 99-272, Sec.9505(a)(2)).

This proposed rule would set forth requirements consistent with requirements in the June 5, 2008 final rule (73 FR 32088) entitled “Medicare and Medicaid Program: Hospice Conditions of Participation.” The hospice care final rule set forth new requirements that a Medicare-certified hospice provider must meet when it provides services, including the provision of hospice care to residents of an LTC facility who elect the hospice benefit. Section 418.112(e) specifies what must be included in a written agreement between a Medicare-certified hospice provider and an LTC facility. We propose making the requirements for LTC facilities consistent with the June 2008 final rule. To this end, the language in this proposed rule was crafted to mirror the hospice final rule as much as possible to ensure that both entities are held equally responsible for the written agreement.

This proposed rule would also support current LTC requirements that protect a resident’s right to a dignified existence, self-determination, and communication with, and access to, persons and services inside and outside the facility.

2. Rationale for new requirements

A 2002 Secretary of the Department of Health and Human Services’ (DHHS) Advisory Committee Report and a 2003 Hastings Center Report have identified a lack of coordination between LTC facilities and Medicare-certified hospice providers. In 2002, the Secretary of DHHS’ Advisory Committee on Regulatory Reform developed recommendations to address key regulatory issues. One of the recommendations of the DHHS Secretary’s Advisory Committee report was to clarify the relationship between nursing facilities and hospice providers. The DHHS Secretary’s Advisory Committee report stated that there was a need to “reconcile conflicts in regulations and/or guidance that prevent clear delineation as to which entity (LTC facility or the hospice) is required to have the lead

in providing required end-of-life care to SNF residents once they elect their hospice benefit.” The report recommended revising guidance and procedures to recognize hospice care in the context of the SNF survey protocol. The report further recommended that, if necessary, CMS revise the CoPs for Medicare-certified hospices, SNFs, and NFs to ensure beneficiaries’ access to the full range of benefits to which they are statutorily entitled, and to ensure the appropriate entity is accountable for care that should be provided, which is based on a resident’s unique needs (<http://regreform.hhs.gov/finalreport.htm>).

An article in the March/April 2003 Hastings Center Report, “Is discontinuity in palliative care a culpable act of omission?” stated, “Hospice patients sign up to obtain palliative care, regardless of the care setting in which they reside. Part of honoring this obligation requires a hospice to attend to the needs of continuity when the site of care does change.” The article further stated that, while most non-hospice healthcare providers do not follow their terminally ill patients to other care sites, hospice staff are required by the Medicare CoPs at §418.56, as well as by industry and accreditation standards, to both provide and oversee palliative care as the patient moves across care sites with which the hospice has a contractual relationship. The article concludes that continuity of care is optimized by care management across care sites. (True Ryndes, Linda Emanuel, The Hastings Center Report, Hastings-on-Hudson: March/April 2003, page S45). (http://findarticles.com/p/articles/mi_go2103/is_2_33/ai_n7517557/?tag=content;coll)

This proposed rule, therefore, seeks to clarify the role of the LTC facility and the Medicare-certified hospice by requiring clear delineation of each provider’s responsibility for maintaining continuity of care.

The problems LTC facilities and hospices have with the coordination of care, as identified in both the Hastings Center Report and the HHS Secretary's Advisory Committee report, is a direct result of the lack of Medicare requirements specifically related to the provision of contracted hospice care in the current regulatory requirements for LTC facilities. The overall intent of this proposed rule is to promote consistency and continuity of care by requiring that a written agreement between the LTC facility and the Medicare-certified hospice provider clearly identify the responsibilities of each entity when arranging for the provision of hospice services to an LTC resident who elects the hospice benefit. This agreement would be required even if the Medicare-certified hospice and the LTC facility were under common control and/or ownership.

Therefore, in light of the HHS Secretary's Advisory Committee report and Hastings Center Report, and to ensure quality hospice care is provided in a coordinated manner to LTC facility residents who have elected to receive hospice services, we are proposing a new standard at 42 CFR §483.75(r), entitled "Hospice services." At §483.75(r)(1), we propose that LTC facilities that choose to arrange for the provision of hospice services through an agreement with one or more Medicare-certified hospices, must have a signed agreement with the hospice before any hospice care is provided to any resident. In addition, for those LTC facilities that decline to arrange for the provision of hospice services through an agreement with a Medicare-certified hospice provider, we propose that facilities would be required to assist a resident in transferring to a facility that would arrange for the provision of these services when the resident requested such a transfer.

Requirements for discharge and transfer from LTC facilities are specified at §483.12. The current regulations do not specifically address a resident's request for transfer. Thus, an

LTC facility may accept a written or verbal request for transfer. We propose that all transfers would have to be documented in the resident's medical record.

Under this proposed rule, when hospice care is provided by a Medicare-certified hospice in an LTC facility through an agreement, the LTC facility would be required to meet additional requirements specific to written agreements between the two entities. The LTC facility would be required to ensure that the hospice services met professional standards and principles that apply to individuals providing services in the facility, and to ensure the timeliness of the services. The term, "timeliness of services" means that the LTC facility would be required to ensure that, from the time the resident elected the hospice benefit until the services were terminated, the Medicare-certified hospice would provide hospice services meeting the resident's needs in a timely manner, without any delay in the provision of services for the resident. We anticipate that LTC facilities would address timeliness of services in their agreements with hospices, based on resident needs.

We propose requiring the signatures of both an authorized representative of the hospice and an authorized representative of the LTC facility for such agreements. These provisions would have to be met before any hospice care was furnished to an LTC facility resident who elected the hospice benefit.

The purpose of the written agreement would be to ensure that the duties and responsibilities of the hospice and the LTC facility were clearly described. The signature requirement would prevent misunderstandings that could affect resident care because a responsible person representing each provider would be aware of the respective roles of each entity under the agreement. In addition, the written agreement would ensure that

mechanisms were in place to ensure needs of the resident were identified and met, including the need for high quality hospice care.

Under the agreement between the LTC facility and the hospice, the hospice would be responsible for making decisions related to a resident's care for the palliation and management of the terminal illness and related conditions, because §418.58 requires a hospice to establish and maintain a written plan of care for every individual admitted to its hospice program. The LTC facility would be responsible for making decisions that were not related to a resident's terminal illness, because §483.20(k) requires a LTC facility to develop a comprehensive care plan for each resident that meets the resident's medical, nursing, mental, and psychosocial needs. Under this proposed rule, the LTC facility would also be responsible for ensuring the hospice provider was informed about changes made to the resident's care plan.

In general, a care plan is a document that provides a "road map" for everyone who is involved with a patient's care. The care planning process includes the interdisciplinary team that will be involved in the care of the patient. The ultimate purpose of a care plan is to guide all involved in the care of the patient in providing the appropriate treatment to ensure an optimal outcome for the patient. A healthcare worker should be able to find all the information needed to care for an individual in that person's care plan.

To encourage the completeness of patient information available to all staff responsible for the care of the patient, we are proposing to require that any written agreements would need to delineate: (1) which services the hospice would provide and which services the LTC facility would continue to provide, as delineated in the care plans; (2) how the LTC facility and hospice would communicate to ensure that needs of residents were

being addressed and met; and (3) the conditions under which the LTC facility would need to contact the hospice immediately (specifically, this would include significant changes in the resident's physical, mental, social, or emotional status; clinical complications that suggested a need to alter the care plan; a need to transfer the resident from the LTC facility for any condition not related to the terminal condition; or resident death).

As stated above, we are also specifically proposing at §483.75(r) (2)(ii)(D) that the written agreement identify a specific method of communication between the LTC facility staff and the hospice staff to ensure the effectiveness and timeliness of care. In an emergency, staff could communicate orally, but we would expect facilities to use best practices and document the communication so there could be appropriate follow-up. Best practices are similar to the term "professional standards of quality," which is defined in current guidelines for surveyors in the State Operations Manual (SOM) (http://www.cms.hhs.gov/manuals/Downloads/som107ap_pp_guidelines_ltc.pdf).

The term "best practices" means that services are provided according to recognized standards of clinical practice. Standards may apply to care provided by a particular clinical discipline or in a specific clinical situation or setting. Standards regarding quality care practices may be established by professional organizations, licensing boards, accreditation bodies, and/or regulatory agencies.

In addition to these requirements for the written agreement, we are proposing that the agreement include a provision stating that the hospice assumes responsibility for determining the appropriate course of hospice care, including changing the level of services provided, if necessary. Among the LTC facility's responsibilities under the written agreement, we are proposing that the agreement include a provision requiring the LTC facility to furnish 24-

hour room and board care, meet the resident's personal care and nursing needs in coordination with the hospice representative, and ensure that the level of care provided is appropriate based on the individual resident's needs.

We are proposing that, under the written agreement, there also be a delineation of the hospice's responsibilities, which include, but are not limited to the following: providing medical direction and management of the patient's hospice care; nursing; counseling (including spiritual, dietary and bereavement); social work; providing medical supplies, durable medical equipment and drugs necessary for the palliation of pain and symptoms associated with the terminal illness and related conditions; and all other hospice services that are necessary for the care of the resident's terminal illness and related conditions.

For example, the written agreement might state that the hospice would be responsible for determining the correct medication for the terminal condition, but the LTC facility staff would be responsible for the medication's administration, because the LTC facility provides 24-hour care for its residents. Delineating responsibility for these key services would ensure not only continuity of care, but would also guarantee appropriate care in a timely manner. For example, if a resident were in pain and needed medication, it would be vital to the care of the resident to have a clear delineation of each provider's specific responsibilities regarding pain control, including all steps from contacting the prescribing practitioner to obtaining medication, following the procedures set up by the hospice, administering the medication and monitoring its effectiveness.

We propose at §483.75(r)(2)(ii)(I) that when the LTC facility personnel are responsible for the administration of prescribed therapies, including those therapies determined by the hospice and delineated in the hospice plan of care, the LTC facility

personnel may be permitted to administer the therapies where permitted by State law and as specified by the LTC facility.

We propose at §483.75(r)(2)(ii)(J) that the LTC facility report all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property by hospice personnel, to the hospice administrator immediately when the LTC facility becomes aware of the alleged violation. This requirement would assure that the hospice is made aware of the alleged violation in a timely manner so that it can begin its own investigation and implement its own intervention(s). We note that under current regulations at §483.13(c)(3), an LTC facility must immediately provide protection for the resident continuing throughout the investigation. The hospice final rule includes a similar provision at §418.112(c)(8), which requires reporting of alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property by LTC facility personnel to the facility administrator. Such provisions enhance LTC facility-hospice communication and cooperation.

We propose at §483.75(r)(2)(ii)(K) that the agreement include a delineation of the responsibilities of the hospice to offer bereavement services to LTC facility staff. We propose at §483.75(r)(3) that each LTC facility that arranges for the provision of hospice care through a written agreement designate a member of the facility's interdisciplinary team to be responsible for working with hospice representatives to coordinate care provided by the LTC facility staff and the hospice staff. In addition, the designated interdisciplinary team member would be responsible for: (1) collaborating with hospice representatives and coordinating LTC facility staff participation in the hospice care planning process for those residents

receiving these services; (2) communicating with hospice representatives and other healthcare providers participating in the provision of care for the terminal illness and related conditions, as well as other conditions, to ensure quality of care for the patient and family; (3) ensuring that the LTC facility communicates with the hospice medical director, the patient's attending physician, and other physicians participating in the provision of care as needed to coordinate the hospice care of the hospice patient with the medical care provided by other physicians; (4) obtaining information from the hospice, including the most recent hospice plan of care specific to each patient, the hospice election form, any advance directives specific to each patient, and physician certification and recertification of the terminal illness specific to each patient, as well as names and contact information for hospice personnel involved in hospice care of each patient; instructions on how to access the hospice's 24-hour on-call system; hospice medication information specific to each patient; and hospice physician and attending physician (if any) orders specific to each patient. In addition, we propose requiring that the LTC facility staff provide orientation to relevant hospice staff about the facility's policies and procedures, including patient rights, appropriate forms, and record keeping requirements.

These proposed requirements would apply regardless of the financial and/or ownership relationship between the LTC facility and the hospice.

Although we believe such orientation is critical for the protection of residents receiving hospice care, we understand that it may be difficult for an LTC facility to properly orient other hospice staff who, in unexpected circumstances, may occasionally provide coverage for a member of the identified hospice interdisciplinary group (IDG). Therefore, we

welcome public comment on how LTC facilities can provide orientation for hospice staff that is quick and efficient but sufficient to protect residents who receive hospice care.

Our intention is to ensure continuity of care by involving designated representatives from both the LTC facility and the hospice in the hospice care planning and hospice care implementation processes, as well as in LTC facility processes. The LTC facility would have the flexibility to assign one employee from the facility's interdisciplinary team as a coordinator for all hospice residents, or assign a separate coordinator for each hospice resident. The designated coordinator would ensure that the hospice plan of care and the LTC facility plan of care were implemented and updated as appropriate. "Interdisciplinary team" refers to the professionals who work together to provide services to the resident, as defined at §483.20(k)(2)(ii). Interdisciplinary team members may include physicians, nurses, therapists, social workers, dietitians, and other professionals, such as developmental disabilities specialists. Involvement of other disciplines is dependent upon resident needs.

We propose at §483.75(r)(4) that each LTC facility that arranges for hospice care under a written agreement with a Medicare-certified hospice ensure that each resident's written plan of care includes both the hospice plan of care and a description of the services furnished by the LTC facility to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being, as required at §483.20(k). We expect that the LTC facility's designated coordinator would work with hospice representatives to meet this requirement.

We believe that including the hospice plan of care (which addresses care for the terminal condition and related conditions) with the LTC facility care plan would improve care coordination and result in better implementation of the overall plan of care. We believe

these proposed requirements would facilitate effective communication and coordination between the Medicare-certified hospice provider and the LTC facility, ensuring that quality care would be provided to residents receiving hospice services. We note that these proposed requirements would not limit the scope of the relationship between the Medicare-certified hospice and the facility. Each party could add provisions, subject to mutual agreement, as long as they met or exceeded the proposed requirements.

We anticipate that these proposed requirements, aimed at improving the coordination of care between LTC facilities and Medicare-certified hospice care providers, would lead to improved consistency and quality of care for LTC facility residents who elect to receive hospice services.

In addition, we are taking this opportunity to make a technical correction due to an incorrect citation at §483.10(n). The language states, “An individual resident may self-administer drugs if the interdisciplinary team, as defined by §483.20(d)(2)(ii), has determined that this practice is safe.” However, §483.20(d)(2)(ii) does not exist. The correct citation is §483.20(k)(2)(ii). In §483.10(n), we are proposing that the reference “§483.20(d)(2)(ii)” be revised to read “§483.20(k)(2)(ii).”

3. Relevance to Existing Hospice Requirements

Our intent in proposing these requirements for LTC facilities is to ensure they are in accord with our existing requirements at §418.112 for hospices that provide services to residents of LTC facilities. Our proposed requirements for LTC facilities to have agreements with hospices and to collaborate and communicate with hospices to provide care for LTC facility residents largely parallels the language and intent of the hospice requirements. There are, however, instances where employing the same language would not reflect the distinct

roles of each entity or where we believe it is important to provide clarity and detail without disturbing the substance or the proper interpretation of the requirements. In some instances, we are proposing different requirements because we believe they are in the best interests of the residents of LTC facilities. For instance, at proposed §483.75 (r)(2)(ii)(J), the LTC facility would be required to report all alleged violations by hospice personnel to the hospice administrator immediately when the LTC facility becomes aware of the alleged violation. However, the hospice is required at §418.112(c)(8) to report these same violations within 24 hours of the hospice becoming aware of the alleged violation.

The rationale for both these rules is to require a written agreement between the hospice and the LTC facility. (See §418.112 (c)(1) through (9) and proposed §483.75 (r) (2)(ii) (A) through (K).) While the rules have slight differences in language, substantively, the requirements are the same. We believe it is appropriate for the remainder of the rule, including the coordination of care requirements at proposed §483.75 (r) (3) (i)(v) and §418.112 (e), to reflect the difference in the roles between the LTC facility and the hospice in providing resident care. Therefore, we are proposing requirements for communication and collaboration specific to the LTC facility that do not mirror the language in the hospice requirements. Rather, the proposed rule for LTC facilities would complement the hospice requirements, and our objective is that, together, these rules will allow for better coordination of care and quality of care for LTC facility residents.

Notwithstanding our analysis that these rules are complimentary and substantively similar, and in view of the slight differences between these rules, we are requesting public comment on whether the differences found in the proposed rule would create a barrier to

forming agreements between LTC facilities or interfere in coordination of residents' care between LTC facilities and hospices.

II. Provisions of the Proposed Regulations

As stated above, we are proposing a new standard at 42 CFR §483.75(r), entitled "Hospice services." At §483.75(r)(1), we propose that LTC facilities may either arrange for the provision of hospice services through an agreement with one or more Medicare-certified hospice providers or not arrange for such services and assist a resident in transferring to a facility that will arrange for the provision of these services when the resident requests such a transfer.

At §483.75(r)(2)(i) and (ii), we propose specific requirements for LTC facilities choosing to have hospice care provided by a Medicare-certified hospice in their facility. The LTC facility would be required to ensure that the hospice services met professional standards and principles that would apply to individuals providing services in the facility, and the timeliness of the services. We also propose requiring that, before any hospice care was provided to a facility resident, a written agreement would have to be signed by both an individual authorized by the hospice administration and an individual authorized by the LTC facility administration.

In addition, under this section, we are proposing that the written agreement would have to include, at the very least, the following provisions:

- Under §483.75(r)(2)(ii)(A), the services the hospice will provide;
- Under §483.75(r)(2)(ii)(B), the hospice's responsibilities for determining the appropriate hospice plan of care as specified in §418.112 (d) of this chapter;

- Under §483.75(r)(2)(ii)(C), the services the LTC facility will continue to provide, based on each resident's care plan; and

- Under §483.75(r)(2)(ii)(D), a communication process, including how the communication will be documented between the LTC facility and the hospice provider, to ensure that the needs of the resident are addressed and met 24 hours per day.

Additionally, under §483.75(r)(2)(ii), we are proposing the inclusion of other duties and responsibilities that must be delineated by the LTC facility and the hospice in their written agreement. Under §483.75(r)(2)(ii)(E), we are proposing that the agreement contain a provision that the LTC facility must notify the hospice provider immediately regarding--

- A significant change in the resident's physical, mental, social, or emotional status;
- Any clinical complication(s) that would suggest a need to alter the plan of care;
- A condition unrelated to the terminal condition that might require transfer of the resident from the facility; or

- The resident's death.

We propose at §483.75(r)(2)(ii)(F) that the hospice must assume responsibility for determining the appropriate course of hospice care, including the determination to change the level of services provided.

We propose at §483.75(r)(2)(ii)(G) that the LTC facility must continue to provide 24-hour room and board care, meet the resident's personal care and nursing needs in coordination with the hospice representative, and ensure that the level of care provided is appropriate based on the individual resident's needs.

At §483.75(r)(2)(ii)(H), we are proposing that the written agreement include a delineation of additional hospice responsibilities, which include, but are not limited to:

- Providing medical direction and management of the patient.
 - Nursing.
 - Counseling (including spiritual, dietary, and bereavement).
 - Social work; providing medical supplies, durable medical equipment, and drugs necessary for the palliation of pain and symptoms associated with the terminal illness and related conditions.
- All other hospice services that are necessary for the care of the resident's terminal illness and related conditions.

We propose at §483.75(r)(2)(ii)(I) that the agreement include a provision that the hospice may use LTC facility personnel, where permitted by State law and as specified by the LTC facility, to assist in the administration of prescribed therapies included in the hospice plan of care.

We are also specifically proposing, at §483.75(r)(2)(ii)(J), that the written agreement contain a provision that the LTC facility must report all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property by hospice personnel, to the hospice administrator immediately when the LTC facility becomes aware of the alleged violation. We propose at §483.75(r)(2)(ii)(K) that the agreement must also include a delineation of the responsibilities of the hospice to offer bereavement services to LTC facility staff.

At §483.75(r)(3)(i) through (v), we are proposing that the LTC facility that arranges for the provision of hospice care under a written agreement must designate a member of the facility's interdisciplinary team to be responsible for working with hospice representatives to

coordinate care provided by the LTC facility and hospice staff to the resident. This individual must be responsible for:

(1) Collaborating with hospice representatives and coordinating LTC facility staff participation in the hospice care planning process for those residents receiving these services;

(2) Communicating with hospice representatives and other healthcare providers participating in the provision of care for the terminal illness, related conditions, and other conditions to ensure quality of care for the patient and family;

(3) Ensuring that the LTC facility communicates with the hospice medical director, the patient's attending physician, and other physicians participating in the provision of care to the patient as needed to coordinate the hospice care of the hospice patient with the medical care provided by other physicians;

(4) Obtaining pertinent information from the hospice (that is, the most recent hospice plan of care specific to each patient; hospice election form and any advance directives specific to each patient; physician certification and recertification of the terminal illness specific to each patient; names and contact information for hospice personnel involved in hospice care of each patient; instructions on how to access the hospice's 24-hour on-call system; hospice medication information specific to each patient; and hospice physician and attending physician (if any) orders specific to each patient); and

(5) Ensuring that the LTC facility staff provide orientation in the policies and procedures of the facility, including patient rights, appropriate forms, and record keeping requirements, to hospice staff furnishing care to LTC residents.

At §483.75(r)(4), we are proposing that each LTC facility providing hospice care under a written agreement must ensure that each resident's written plan of care includes both

the hospice plan of care and a description of the services furnished by the LTC facility to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being, as required at §483.20(k).

As stated in the previous section above, we are also taking this opportunity to make a technical correction due to an incorrect citation at §483.10(n). In §483.10(n), we are proposing that the reference “§483.20(d)(2)(ii)” be revised to read “§483.20(k)(2)(ii).”

III. Collection of Information Requirements

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

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

Proposed §483.75(r)(2)(ii) states that if hospice care is provided in an LTC facility through an agreement with a Medicare-certified hospice, the LTC facility must have a written agreement with the Medicare-certified hospice before care is furnished to any resident.

An LTC facility would be required to have only one written agreement with each hospice that provides services in the facility. This proposed rule would not require an LTC facility to have an individual agreement with a hospice for each resident receiving hospice services. Therefore, the burden associated with this requirement is the time and effort necessary for an LTC facility to develop and finalize one written agreement. Initially, the development of an agreement would require staff time; however, it would also require additional staff time to coordinate the care between the hospice and the LTC facility.

We estimate the number of hours to develop and finalize a written agreement to be approximately 5 hours the first year. The estimated burden associated with the first year is 80,695 hours or \$5,512,275. The current requirements at §483.75(h) “Use of Outside Resources,” requires a written agreement when contracting for outside services. Therefore, we would expect that a facility would modify an existing agreement to make it specific to hospice services. Review and revision of an already existing agreement would be expected to take less time thereafter. We estimate that it would take 2 hours to review and revise the agreement annually. The estimated annual burden associated with each successive year after the first is 32,278 hours or \$2,204,910. We have based our projections of the hourly cost on the rate for a staff lawyer at \$68.31 an hour, which includes fringe benefits (estimated to be 25 percent of the salary). (Source: Bureau of Labor Statistics, Occupational Employment Statistics Survey.)

Proposed sections 483.75(r)(2)(ii)(E)(1) through (4) state that the LTC must notify the hospice immediately about--

- A significant change in the resident's physical, mental, social, or emotional status;
- Clinical complications that suggest a need to alter the plan of care;
- A need to transfer the resident from the facility for any condition that is not related to the terminal condition; or
- The resident's death.

The burden associated with these requirements is the time and effort it would take the LTC facility to provide notification to the hospice. We estimate it would take approximately 5 minutes per notification. We anticipate that this would affect 16,139 LTC facilities. If each LTC facility makes 1 notification each month, the burden associated with this requirement is 16,139 annual burden hours and the cost would be \$504,344 annually, based on an hourly rate of \$31.25 for a blended salary of a registered nurse and licensed practical nurse that includes fringe benefits, since either practitioner could notify the hospice of stated changes. (Source: Bureau of Labor Statistics, Occupational Employment Statistics Survey).

Proposed §483.75(r)(2)(ii)(J) states that under the agreement, the LTC facility must report all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and misappropriation of patient property by hospice personnel to the hospice administrator immediately when the LTC facility becomes aware of the alleged violation. The burden associated with this requirement is the time and effort it would take the LTC facility to report this information to the hospice administrator. We estimate it would take approximately 10 minutes per incident. We anticipate that this would affect 16,139 LTC facilities. If each LTC facility made one report

per month, the burden associated with this requirement would be 32,278 annual burden hours and the cost would be \$1,032,895 annually based on an hourly rate of \$32 for a registered nurse that includes fringe benefits. (Source: Bureau of Labor Statistics, Occupational Employment Statistics Survey)

Estimated Annual Reporting and Recordkeeping Burden

Regulation Section(s)	OMB Control No.	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting (\$)	Total Labor Cost of Reporting (\$)	Total Capital/Maintenance Costs (\$)	Total Cost (\$)
§483.75(r)(2)(ii)	0938-New	16,139	16,139	5	80,695*	68.31	5,512,275	0	5,512,275
		16,139	16,139	2	32,278**	68.31	2,204,910	0	2,204,910
§483.75(r)(2)(ii)(E)(1-4)	0938-New	16,139	193,668	.08333	16,139	31.25	504,344	0	504,344
§483.75(r)(2)(ii)(J)	0938-New	16,139	193,668	.16666	32,278	32.00	1,032,895	0	1,032,895
Total		16,139	209,807		161,390				9,254,424

*One time burden estimate for initial development of written agreement.

**Annual burden estimate associated with updating existing written agreements.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the ADDRESSES section of this proposed rule; or
2. Mail copies to the address specified in the ADDRESSES section of this proposed rule and to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, CMS-3140-P

Fax: (202) 395-6974; or

Email: OIRA_submission@omb.eop.govIV.

Response to Comments

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

V. Regulatory Impact Analysis

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 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This rule does not qualify as a major rule as the estimated economic impact is \$7,049,515 the first year and \$3,742,150 thereafter.

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. The great majority of hospitals and most other health care

providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than \$7.0 million to \$34.5 million in any 1 year). For purposes of the RFA, the majority of hospitals, LTC facilities and hospices are considered to be small entities. Individuals and States are not included in the definition of a small entity. A rule has a significant economic impact on the small entities it affects, if it significantly affects their total costs or revenues. Under statute, we are required to assess the compliance burden the regulation will impose on small entities. Generally, we analyze the burden in terms of the impact it will have on entities' costs if these are identifiable or revenues. As a matter of sound analytic methodology, to the extent that data are available, we attempt to stratify entities by major operating characteristics such as size and geographic location. If the average annual impact on small entities is 3 to 5 percent or more, it is to be considered significant. We estimate that these requirements would cost \$437 (\$7,049,515/ 16,139 facilities) per facility initially and \$232 (\$3,742,150 /16,139 facilities) thereafter. This clearly is much below 1 percent; therefore, we do not anticipate it to have a significant impact. We do not have any data related to the number of LTC facilities contracting hospice care through an outside hospice provider; however, we are aware through annual surveys that not all LTC facilities arrange for the provision of hospice care.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For the 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 rule would impact only long-term care facilities. Therefore, the Secretary has

determined that this proposed rule would not have any impact on the operations of small rural hospitals.

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 2010, that threshold is approximately \$135 million. This rule would not have a significant impact on the governments mentioned or on private sector costs. The estimated economic effect of this rule is \$7,049,515 the first year and \$3,742,150 thereafter. These estimates are derived from our analysis of burden associated with these requirements in section III, “Collection of Information Requirements.”

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule will not have any effect on State or local governments.

B. Anticipated Effects

1. Effects on LTC facilities

The purpose of this rule is to ensure the coordination of care for LTC facility residents who elect hospice services. The coordination of care is anticipated to result in better outcomes related to quality of care and quality of life for residents. With appropriate coordination of care as proposed in this rule, we anticipate improved outcomes through more efficient coordination of care between the LTC facility staff and hospice staff, a decrease in duplication of services provided, and improved resident care.

2. Effects on Other Providers

We expect improved consistency in the provision of services to residents receiving hospice care in an LTC facility. We anticipate that primarily only LTC facilities and Medicare-certified hospice providers would be affected, as this proposed rule would be expected to improve coordination of care between LTC facilities and Medicare-certified hospice providers. In instances where a patient is transferred to the hospital for care unrelated to their terminal illness, the hospital should be notified that the patient has elected hospice care.

3. Effects on the Medicare and Medicaid Programs

An Office of the Inspector General (OIG) report released in 1997 found that "contractual arrangements between hospice providers and nursing homes present vulnerabilities for inappropriate use of excessive Medicare and Medicaid payments being made to hospice providers or to nursing homes" (U.S. HHS OIG, Hospice and Nursing Home Contractual Relationships, 1997 Nov., OEI-05-95-00251). We anticipate that the proposed rule would decrease these vulnerabilities, as the services provided by both the LTC facility and the Medicare-certified hospice would be clearly defined.

C. Alternatives Considered

We considered the effects of not addressing specific requirements for the provision of hospice care in LTC facilities. However, we believe that to improve quality and ensure consistency in the provision of hospice services in LTC facilities, it is important to delineate clear responsibilities for Medicare-certified hospice providers and LTC facilities. We expect that these requirements would result in improvement in the quality of care provided to LTC residents receiving hospice services.

D. Conclusion

This proposed rule for a written agreement when arranging for the provision of hospice services in LTC facilities is intended to improve the continuity and quality of care provided to terminally ill LTC facility residents. It is consistent with the Administration's efforts toward broad-based improvements in the quality of health care furnished by Medicare and Medicaid providers.

This proposed rule identifies an LTC facility's choices if a resident elects to receive hospice care. This proposed rule also clarifies the responsibility of the facility that chooses not to arrange for the provision of hospice services at the facility through an agreement with a Medicare-certified hospice. These facilities must assist the resident in transferring to a facility that will arrange for the provision of hospice services when a resident requests a transfer.

This proposed rule would ensure that the duties and responsibilities of a hospice are clearly articulated if the hospice provides care in an LTC facility. Therefore, in order to ensure that quality hospice care is provided to LTC residents we believe it is essential to add these proposed requirements to the LTC regulations.

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.

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

PART 483--REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

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

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

Subpart B--Requirements for Long Term Care Facilities

§ 483.10 [Amended]

2. In § 483.10(n), the reference “§ 483.20(d)(2)(ii)” is revised to read “§ 483.20(k)(2)(ii).”

3. Section 483.75 is amended by adding paragraph (r) to read as follows--

§ 483.75 Administration.

* * * * *

(r) Hospice services. (1) A long-term care (LTC) facility may either –

(i) Arrange for the provision of hospice services through an agreement with one or more Medicare-certified hospices; or

(ii) Not arrange for the provision of hospice services at the facility through an agreement with a Medicare-certified hospice and assist the resident in transferring to a facility that will arrange for the provision of hospice services when a resident requests a transfer.

(2) If hospice care is provided in an LTC facility through an agreement as specified in paragraph (r)(1)(i) of this section with a hospice, the LTC facility must:

(i) Ensure that the hospice services meet professional standards and principles that apply to individuals providing services in the facility, and to the timeliness of the services.

(ii) Have a written agreement with the hospice that is signed by an authorized representative of the hospice and an authorized representative of the LTC facility before hospice care is furnished to any resident. The written agreement must set out at least the following:

(A) The services the hospice will provide.

(B) The hospice's responsibilities for determining the appropriate hospice plan of care as specified in § 418.112(d) of this chapter.

(C) The services the LTC facility will continue to provide, based on each resident's care plan.

(D) A communication process, including how the communication will be documented between the LTC facility and the hospice provider, to ensure that the needs of the resident are addressed and met 24 hours per day.

(E) A provision that the LTC facility immediately notifies the hospice regarding--

(1) A significant change in the resident's physical, mental, social, or emotional status;

(2) Clinical complications that suggest a need to alter the plan of care;

(3) A need to transfer the resident from the facility for any condition that is not related to the terminal condition; or

(4) The resident's death.

(F) A provision stating that the hospice assumes responsibility for determining the appropriate course of hospice care, including the determination to change the level of services provided.

(G) An agreement that it is the LTC facility's responsibility to furnish 24-hour room and board care, meet the resident's personal care and nursing needs in coordination with the hospice representative, and ensure that the level of care provided is appropriate based on the individual resident's needs.

(H) A delineation of the hospice's responsibilities, which include, but are not limited to, providing medical direction and management of the patient; nursing; counseling (including spiritual, dietary, and bereavement); social work; providing medical supplies, durable medical equipment, and drugs necessary for the palliation of pain and symptoms associated with the terminal illness and related conditions; and all other hospice services that are necessary for the care of the resident's terminal illness and related conditions.

(I) A provision that when the LTC facility personnel are responsible for the administration of prescribed therapies, including those therapies determined by the hospice and delineated in the hospice plan of care, the LTC facility personnel may administer the therapies where permitted by State law and as specified by the LTC facility.

(J) A provision stating that the LTC facility must report all alleged violations involving mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including

injuries of unknown source, and misappropriation of patient property by hospice personnel, to the hospice administrator immediately when the LTC facility becomes aware of the alleged violation.

(K) A delineation of the responsibilities of the hospice and the LTC facility to provide bereavement services to LTC facility staff.

(3) Each LTC facility arranging for the provision of hospice care under a written agreement must designate a member of the facility's interdisciplinary team to be responsible for working with hospice representatives to coordinate care to the resident provided by the LTC facility staff and hospice staff. The designated interdisciplinary team member is responsible for:

(i) Collaborating with hospice representatives and coordinating LTC facility staff participation in the hospice care planning process for those residents receiving these services.

(ii) Communicating with hospice representatives and other healthcare providers participating in the provision of care for the terminal illness, related conditions, and other conditions, to ensure quality of care for the patient and family.

(iii) Ensuring that the LTC facility communicates with the hospice medical director, the patient's attending physician, and other physicians participating in the provision of care to the patient as needed to coordinate the hospice care with the medical care provided by other physicians.

(iv) Obtaining the following information from the hospice:

(A) The most recent hospice plan of care specific to each patient;

(B) Hospice election form and any advance directives specific to each patient;

(C) Physician certification and recertification of the terminal illness specific to each patient;

(D) Names and contact information for hospice personnel involved in hospice care of each patient;

(E) Instructions on how to access the hospice's 24-hour on-call system;

(F) Hospice medication information specific to each patient; and

(G) Hospice physician and attending physician (if any) orders specific to each patient.

(v) Ensuring that the LTC facility staff provide orientation in the policies and procedures of the facility, including patient rights, appropriate forms, and record keeping requirements, to hospice staff furnishing care to LTC residents.

(4) Each LTC facility providing hospice care under a written agreement must ensure that each resident's written plan of care includes both the most recent hospice plan of care and a description of the services furnished by the LTC facility to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being, as required at §483.20(k).

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

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare--Hospital

Insurance; and Program No. 93.774, Medicare--Supplementary Medical Insurance Program)

Dated: May 27, 2010

Donald M. Berwick,

Administrator,

Centers for Medicare & Medicaid Services.

Approved: October 1, 2010

Kathleen Sebelius,

Secretary.

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