



This document is scheduled to be published in the Federal Register on 06/27/2013 and available online at <http://federalregister.gov/a/2013-15313>, and on FDsys.gov

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 483

CMS-3140-F

RIN 0938-AP32

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

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

ACTION: Final rule.

SUMMARY: This final rule will revise the requirements that an institution will 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. These requirements will ensure that long-term care (LTC) facilities (that is, SNFs and NFs) that choose to arrange for the provision of hospice care through an agreement with one or more Medicare-certified hospice providers will have in place a written agreement with the hospice that specifies the roles and responsibilities of each entity. This final rule reflects the Centers for Medicare and Medicaid Services' (CMS') commitment to the principles of the President's Executive Order 13563, released on January 18, 2011, titled "Improving Regulation and Regulatory Review." It will improve quality and consistency of care between hospices and LTC facilities in the provision of hospice care to LTC residents.

DATES: These regulations are effective on [OFR: insert date 60 days after publication in the Federal Register.]

FOR FURTHER INFORMATION CONTACT:

Lisa Parker, (410) 786-4665.

SUPPLEMENTARY INFORMATION:

I. Background

A. 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 (SNF) or nursing facility (NF) 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, and specified that such care could be provided to an individual while such individual was a resident of a SNF or intermediate care facility (Pub. L. 99-272 (1986), section 9505(a)(2)). Additionally, eligible residents of long-term care (LTC) facilities may elect to receive services under the Medicare hospice benefit.

Medicare does not have a separate payment rate for routine hospice services provided in a nursing home. Because hospice services are typically provided to patients in their homes, the routine home care hospice rate does not include any payment for room or board. For routine home care services provided to patients in LTC facilities, hospices receive the Medicare routine home care rate, which is a fixed amount per day for the services provided by the hospice, regardless of the volume or intensity of the services provided. Accordingly, when the hospice patient resides in an LTC facility, the patient generally remains responsible

for payment of the LTC facility's room and board charges. If, however, a patient receiving Medicare hospice benefits in an LTC facility is also eligible for Medicaid, Medicaid will pay the hospice at least 95 percent of the State's daily LTC facility rate, and the hospice is then responsible for paying the LTC facility for the beneficiary's room and board. The specific services included in the daily rate payment are determined by the State's Medicaid program and may vary from State to State. In addition to the room and board payment, a hospice may contract with the nursing home for the nursing home to provide non-core hospice services (that is, those services which the hospice is not required by law to provide itself) to its hospice patients.

LTC facilities and hospices are required to provide many of the same services to residents who have elected to receive the hospice benefit. The LTC facility regulations clearly specify what services the facility is required to provide to residents. Those services include nursing services (including aide services), dietary services, physician services, dental services, pharmacy services, specialized rehabilitative services if appropriate, laboratory services, and social services. Similarly, if a resident chooses to elect the hospice benefit, hospice providers are required to provide many of the same services as the LTC facility. As required at 42 CFR 418.100(c), a hospice must provide certain specified care and services and must do so in a manner that is consistent with accepted standards of practice. Those services include nursing services (including aide services), medical social services, physician services, counseling services (spiritual, dietary, and bereavement), volunteer services, therapy services as appropriate, short-term inpatient care, and medical supplies.

Due to so many of the same services being provided by both LTC facilities and hospice providers, there is a clear potential for residents to receive duplicative and/or

conflicting services. The Department of Health and Human Services' Office of Inspector General (OIG) has recently raised a number of concerns about Medicare hospice care for nursing facility residents. OIG found that 31 percent of Medicare hospice beneficiaries resided in nursing facilities in 2006 and that 82 percent of hospice claims for these beneficiaries did not meet Medicare coverage requirements. (OIG, Medicare Hospice Care: Services Provided to Beneficiaries Residing in Nursing Facilities, OEI-02-06-00223, September 2009). Additionally, OIG reported that, unlike private homes, nursing facilities are staffed with professional caregivers and are often paid by third-party payers, such as Medicaid. These facilities are required to provide personal care services, which are similar to hospice aide services that are paid for under the hospice benefit. (OIG, Medicare Hospices that Focus on Nursing Facility Residents, OEI-02-10-00070, July 2011). To address this issue, we are establishing a requirement that will ensure LTC facilities that choose to arrange for the provision of hospice care through an agreement with one or more Medicare-certified hospice providers will have in place a written agreement with the hospice that will specify the roles and responsibilities of each entity. These clarifications will increase coordination of care for patients as well as help foster a stronger channel of communication between the two providers assisting patients and their families. We believe that a clear division of responsibilities and increased communication required by this rule will help eliminate duplication of and/or missing services.

This final rule sets forth requirements consistent with requirements in the June 5, 2008 final rule (73 FR 32088) titled "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. In regulations at 42 CFR §418.112(c), we specify what must be included in a written agreement between a Medicare-certified hospice provider and an LTC facility. In this final rule, we have made the requirements for LTC facilities consistent with the June 2008 final rule.

This final rule also supports 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.

B. Relevance to Existing Hospice Requirements

Our intent in finalizing 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 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 will 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 finalizing different requirements because we believe they are in the best interests of the residents of LTC facilities. For instance, we are requiring at §483.75(t)(2)(ii)(E)(3) that the LTC facility notify the hospice about a need to transfer the resident from the facility for any condition. As a slight variation, the hospice is currently required at §418.112(c)(2)(iii) to provide in an agreement with a SNF/NF or ICF/IID that the SNF/NF or ICF/IID will notify the hospice of a need to transfer a patient from the SNF/NF or ICF/IID, and the hospice makes arrangements for, and remains responsible for necessary continuous care or inpatient

care related to the terminal illness and related conditions. While these provisions are similar, the hospice regulations also highlight the hospice's continued responsibility for care related to the terminal illness. We believe that these provisions, which are tailored to the unique needs and circumstances of each provider type, will promote higher quality of care and safety for the resident.

The rationale for both of these rules is to require a written agreement between the hospice and the LTC facility, which will help ensure safe and quality care if provided to the residents. (See §418.112 (c)(1) through (9) for hospice and §483.75(t)(2)(ii) (A) through (K) finalized in this rule for LTC facilities.) 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 §483.75(t)(3)(i) through (v) for LTC facilities and §418.112(e) for hospice, to reflect the difference in the roles between these two providers in delivering resident care. Therefore, we are finalizing requirements for communication and collaboration specific to the LTC facility that do not entirely mirror the language in the hospice requirements. Rather, the final rule for LTC facilities will complement the hospice requirements, and together, these rules will allow for better coordination of care and quality of care for LTC facility residents who elect to receive the hospice benefit.

This final rule reflects the Centers for Medicare and Medicaid Services' (CMS') commitment to the principles of the President's Executive Order 13563, released on January 18, 2011, titled "Improving Regulation and Regulatory Review." It will improve quality and consistency of care between hospices and LTC facilities in the provision of hospice care to LTC residents.

II. Provisions of the Proposed Rule and Response to Comments

We published a proposed rule in the **Federal Register** on October 22, 2010 (75 FR 65282). In that rule, we proposed to 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 provided a 60-day public comment period, during which we received approximately 30 timely comments from individuals, advocacy organizations, and industry associations. Summaries of the proposed provisions, as well as the public comments and our responses, are set forth below. We originally proposed the standard regarding LTC facility/Hospice cooperation at §483.75(r); however, during the process of finalizing this rule, CMS published a separate interim final rule, titled “Requirements for Long-Term Care (LTC) Facilities; Notice of Facility Closure” (76 FR 9503). The interim final rule added separate standards at §§483.75(r) and (s). Since the designations (r) and (s) are now in use, we are finalizing this standard at §483.75(t). However, in this discussion, we will continue to refer to the proposed regulations text at §483.75(r).

Comments Regarding Possible Barrier Creation

Notwithstanding our analysis that this rule and 2008 final hospice rule are complimentary and substantively similar, and in view of the slight differences between these rules, we requested public comment on whether the differences found in the proposed rule would create a barrier to forming agreements between LTC facilities and hospices, or interfere in coordination of residents’ care between LTC facilities and hospices. We received a few comments regarding the differences between the two rules. Those comments and our response are set forth below.

Comment: Several commenters had concerns that the proposed rule, as written, has the potential of creating a barrier to agreements between LTC facilities and hospice providers. Commenters noted that this requirement imposes responsibility and liability on the LTC facilities to make decisions regarding whether or not a hospice provider is meeting professional standards and principles. Those duties and responsibilities are the province of the State licensing agency and CMS, and should not be placed on LTC facilities.

Response: The requirements in the final rule will ensure that LTC facilities that chose to arrange for the provision of hospice care through an agreement with one or more Medicare-certified hospice providers will have in place a written agreement with the hospice that specified the roles and responsibilities of each entity. If an LTC facility is establishing an agreement for the provision of services, the LTC facility should be monitoring the delivery of the services to a resident in order to assure that professional standards and principles are followed in the provision of the services within their facility. The LTC facility is responsible for assuring that services and care provided meet the assessed needs of each resident.

General Comments

Comment: The majority of commenters support the rule. Several commenters stated that having a mandated set of written expectations between LTC facilities and hospice providers would help clarify specific responsibilities of each entity. The commenters also stated that clarifications will increase coordination of care for patients as well as help foster a stronger channel of communication between the two providers assisting patients and their families. With a clear division of responsibilities and increased communication, this rule will help eliminate duplication of and/or missing services.

Response: We appreciate the support from the commenters on this proposal. We believe that having a consistent set of regulatory requirements that establish the expectations for both hospices (§418.112(e)) and LTC facilities (§483.75(t)) will help both entities clarify their specific patient/resident-care roles and responsibilities. The regulatory clarity will also help to eliminate duplication of and/or missing services.

Comment: One commenter suggested extending the deadline for the implementation of the rule to allow hospices and LTC facilities more time to develop agreements to be reached, reviewed, and signed along with training of LTC and hospice staff to be conducted.

Response: The rule will be effective on [OFR: insert date 60 days after publication in the Federal Register.] We believe this is an adequate timeframe since hospices already have to meet this requirement.

Comment: Several commenters suggested the final rule should include the creation of a liaison position. Commenters suggested the on-staff, clinically trained professional should serve as a point of contact and mediator collaborating directly with hospice and LTC facility staff members to coordinate effective patient care. Some commenters suggested that the point of contact person be on the LTC facility's staff, while other commenters suggested the position be filled by a member of the hospice staff. Commenters suggested that the liaison position should help to eliminate division of services and ensure that all appropriate medical care safety precautions were being observed and provided.

Response: We believe the requirement that we are finalizing, which designates a member of the LTC facility's interdisciplinary team as a point of contact who will directly collaborate with hospice to coordinate effective patient care sufficiently, addresses the commenter's suggestion. Likewise, current hospice regulations (§418.112(e)(1)) require the

designation of a person who is responsible for coordinating the care of the resident provided by the LTC facility and hospice staff.

Comment: One commenter stated that SNFs and NFs should provide hospice services to residents in their facilities and there should be reimbursement for the care.

Response: The current regulations do not prohibit an LTC facility from providing palliative care to its residents with its own staff. However, we do not have the statutory authority to modify LTC facility payments to include the full range of hospice services. In addition, in order to receive Medicare payment for hospice services, the hospice provider must meet Medicare hospice requirements, including the statutory requirement that a hospice be primarily engaged in providing the hospice care and services set out at section 1861(dd)(1) of the Act. Therefore, under the above statutory requirements an LTC facility could not receive Medicare hospice benefit payments because it is not primarily engaged in providing hospice services and does not meet the definition of a hospice. If a provider does not meet the definition of a “hospice” it cannot be Medicare-certified and therefore, cannot receive payment under the Medicare hospice benefit.

Comment: One commenter mentioned that they disagreed with the increased responsibility that the proposed rule placed on LTC facilities. Another commenter suggested that the focus of the proposed rule was incorrect. Rather than the expense and additional regulation that the proposed rule would generate, the commenter would like each State to provide the guidance for facilities desiring to provide hospice services.

Response: We do not believe that the written agreement and resident care requirements increase an LTC facility’s responsibilities. An LTC facility’s responsibilities for the care of its residents already exist in regulation at §483.25, which states that “each

resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.” The requirements of this final rule simply clarify the roles and responsibilities of LTC facilities when they choose to contract with hospices to serve their residents. For more than a decade, States have regulated the overlapping relationship between LTC facilities and hospice providers. As we explained in the proposed rule, there is clear and consistent evidence of a lack of care coordination and persistent ambiguities in care responsibilities when LTC residents are also hospice patients. Both a 2002 Department of Health and Human Services’ (DHHS) Advisory Committee Report (<http://regreform.hhs.gov/finalreport.htm>) and a 2003 Hastings Center Report (True Ryndes, Linda Emanuel, The Hastings Center Report, Hastings-on-Hudson: March/April 2003, page S45) addressed the need for more care coordination. We believe it is in the best interest of the patients to regulate this overlapping relationship in order to improve the safety and quality of care provided to LTC residents who receive hospice services. Information gathered from surveys in both LTC facilities and hospice providers has informed our policy making for this rule. Furthermore, as this regulation is a companion rule to the current hospice CoPs, the industry has voiced support for this rule because it clarifies the responsibilities of both providers.

Comment: One commenter questioned how this rule affects hospice provision in other types of facilities in which an individual may reside (for example, Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs/IID), formerly referred to as ICFs/MR). The commenter asked if the exclusion of other facilities, for example ICFs/IID,

implies that a State could not provide the hospice benefit, or does it imply that a State has the option to provide hospice?

Response: This regulation specifically clarifies the responsibilities of LTC facilities and hospice providers that choose to have in place a written agreement for hospice services. Therefore, the requirements in this rule will only apply to LTC facilities. However, we believe the commenters concerns regarding hospice services in ICFs/IID are addressed in the current hospice regulations. Section 418.112(c) “Written agreement,” sets forth the requirements for a written agreement between hospice and ICFs/IID. Since this regulation only affects LTC facilities we did not intend to imply anything regarding the State’s ability to provide hospice services.

Notice of Availability of Hospice Services

We proposed a new standard at §483.75(r), titled “Hospice services.” At §483.75(r)(1), we proposed that LTC facilities could 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 would arrange for the provision of these services when the resident requested such a transfer.

Comment: Some commenters believed LTC facilities should be required to provide notice to residents upon admission as to whether hospice care will be available at the facility along with the names of the Medicare-certified hospice providers with which the facility has agreements. Additionally, commenters suggested that LTC facilities should also be required to give notice to their residents should substantial changes occur regarding their agreements with Medicare-certified hospice programs. If the facility has no agreement for the provision of hospice care, commenters suggested that the admission notice should explain to the

resident that hospice care is not available at the facility and include information regarding the facility's responsibility to assist with transfer should the resident become terminally ill and wish to elect the hospice benefit.

Response: We agree with the commenters that notifying residents of services that an LTC facility provides is important. However, we believe that the current requirements at §483.10(b)(6) sufficiently address this issue. Section 483.10(b)(6) currently requires an LTC facility to inform each resident before, or at the time of admission, and periodically during the resident's stay, of all services available in the facility. From past experience with LTC facilities, we would assume that information regarding available hospice services would be discussed at the time in which the resident wishes to utilize the hospice benefit.

Additionally, while it is uncommon for residents to enter an LTC facility and have need of hospice services right away, it can sometimes occur. A resident transferring into an LTC facility with the intention of using his or her hospice benefit right away is more than likely either being discharged from a hospital, or already receiving hospice care at home and in need of care in an LTC facility because the caregiver can no longer meet the individual's custodial care needs. In the event that the resident is being discharged from a hospital and entering an LTC facility opting to use their hospice benefit, the hospital would be responsible for developing an appropriate discharge care plan to an LTC facility that provides hospice services. If the resident is already receiving hospice services at home and chooses to move to an LTC facility, the hospice, through its medical social services, would assist the individual and family in selecting an appropriate LTC facility with a hospice agreement.

Timeliness of Service

At §483.75(r)(2)(i) and (ii), we proposed 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 proposed 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.

Comment: Seven commenters recommended that we clarify the meaning of “timeliness of services.” Commenters also suggested that the interdisciplinary team be responsible for ensuring that the hospice provider is meeting the requirements. Another commenter suggested that the proposed requirement was duplicative of existing conditions of participation (CoPs) for LTC facilities and should be deleted from the final rule.

Response: The term, “timeliness of services” means that the LTC facility will be required to ensure that the Medicare-certified hospice will provide services to the resident in a way that meets their needs in a timely manner, for example, by increasing the resident’s pain medication to ensure an optimal comfort level. We anticipate that LTC facilities will address timeliness of services in their agreements with hospices, based on resident needs. Although the existing LTC facility standard at §483.75(h)(2)(ii) requires the facility to assure the timeliness of the current services that an LTC facility provides, this provision does not specifically apply to the content of written agreements for hospice services. Therefore, the requirement at §483.75(t)(2)(i) is not duplicative. We are finalizing the language as proposed.

Services and Responsibilities of Hospice Plan of Care

We proposed under §483.75(r)(2)(ii)(A) through §483.75(r)(2)(ii)(D) that the written agreement include, at least, descriptions of the services the hospice will provide; the hospice's responsibilities for determining the appropriate hospice plan of care as specified in §418.112(d); the services the LTC facility would continue to provide, based on each resident's care plan; and 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 were addressed and met 24 hours per day.

Comment: One commenter suggested that it would be helpful if there was a standardized communication form that hospice providers and LTC facilities could use to inform each other of new orders and changes, and if it indicated whether or not the primary physician and family member had been notified. Another commenter suggested that the facility document family engagement, consent, acknowledgement of an agreement with the patient's care plan, and any changes requested by the patient or their family in the patient's medical record. This would assist the family and the caregivers in identifying when there was a deviation from the plan of care.

Response: The written agreements between the hospice and the LTC facilities require communication between the two entities regarding the provision of care to the resident receiving hospice services. The LTC facility and hospice must collaborate on how they will communicate information regarding the resident's care and staff must be aware of the system and/or form for communication that will be used. The development of a system and/or form for communication is the responsibility of the hospice and LTC facility. Additionally, we believe that the commenter's suggestion regarding documentation in the resident's medical

record is sufficiently addressed at §483.75(l)(5). That requirement sets forth the information LTC facility clinical records must contain.

Comment: One commenter suggested that CMS update the instructions used by the State Agencies responsible for LTC facility survey and certification to ensure that sufficient emphasis is placed on surveyor review of a facility's clinical and administrative documentation. The commenter stated that this update would assure proper communication between all caregivers, regardless of their employer, and that issues of concern expressed in that documentation would be appropriately addressed by the LTC facility and other providers serving the facility's residents.

Response: We appreciate the commenter's suggestion regarding updates for surveyors. We expect shortly after the publication of the rule that updates to the State Operations Manual (SOM), which among other things provides interpretive guidelines for our surveyors, will be made regarding the new requirements. The instructions to surveyors for reviewing the care of a resident receiving hospice services are found in the interpretive guidelines for §483.25, "Quality of Care." (TAG #F309 in Appendix PP of the SOM). This guidance provides instruction for the surveyor for the review and observation of the delivery of care, and for the review of the collaboration of the services between the hospice and the nursing home, including the coordination of care, the plan of care and the communication between the two entities.

Notifying Hospice of Change in Patient Status

Under §483.75(r)(2)(ii), we proposed 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 proposed that the agreement contain a provision that the LTC

facility notify the hospice provider immediately regarding a significant change in the resident's physical, mental, social, or emotional status, any clinical complication(s) that suggests 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.

Comment: A few commenters stated that hospice providers should be notified of any transfer of a resident receiving hospice services, regardless of whether it was related to the terminal illness or not. Therefore, commenters suggested amending the rule to read, "a need to transfer the resident from the facility for any condition."

Response: We agree with the commenters and have revised the regulation at §483.75(t)(2)(ii)(E)(3) to remove the phrase "that is not related to the terminal condition" in order to clarify that the LTC facility immediately notifies the hospice regarding a need to transfer the resident from the facility for any condition.

Appropriate Level of Hospice Services

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

Comment: One commenter stated that there was often disagreement between hospice staff and LTC facility staff due to hospice providers changing orders unrelated to the terminal diagnosis and/or palliative care. In addition, the commenter stated that hospice providers did not always provide rationale for changed orders. Another commenter expressed difficulty receiving information from local hospice providers in a timely manner; therefore, the commenter thought that this requirement would be difficult to fulfill.

Response: In accordance with the hospice regulations at §418.112(c)(3), the hospice is responsible for establishing and updating the hospice plan of care, which encompasses all issues related to the terminal illness and all related conditions. We encourage LTC facilities and hospices to establish procedures for communicating patient care between both providers, more specifically to determine which provider is responsible for the care planning. For example, both hospice staff and LTC facility staff need to be aware of conditions related to the resident's terminal illness, which are handled under the hospice's care planning. Additionally, they need to be aware of conditions not related to the resident's terminal illness, which are handled under the LTC facility's care planning. Effective communication among both LTC facilities and hospices is, we believe, the most appropriate way for both providers to address this issue. The regulations for the written agreements for the hospice regulations at §418.112(c)(1) and the LTC facility regulations at §483.75(t)(2)(ii)(D) require both entities to establish, in writing, the manner in which they are to communicate with one another, and the method(s) that will be used to document such communications.

Continuation of Appropriate Resident's Needs

We proposed 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.

Comment: A commenter stated that most hospice care, whether in the home or in an LTC facility, is provided at the routine level of care. If an LTC resident elects the Medicare hospice benefit and is receiving a routine level of care, Medicare does not pay for the resident's room and board. This billing caveat frequently creates a great deal of confusion

for Medicare beneficiaries and their families. One commenter suggested that before the start of hospice care in the LTC facility and the consequent financial liability of the Medicare beneficiary for the cost of the room and board, the LTC facility should be required by regulation to provide notice to the beneficiary clearly explaining the liability for room and board and the estimated cost of that liability.

Response: At §418.52(c)(7) of the hospice CoPs, hospice providers are required to ensure that residents receive information about the services covered under the hospice benefit. Likewise, §483.10(b)(6) of the LTC facility regulations, require LTC facilities to inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare or by the facility's per diem rate. Therefore, we believe that the current LTC and hospice regulations address the concerns of the comments.

Additional Hospice Responsibilities

At §483.75(r)(2)(ii)(H), we proposed that the written agreement include a delineation of additional hospice responsibilities, which would include, but not be limited to, providing medical direction and management of the patient; nursing; counseling (including spiritual, dietary, and bereavement); social work; and the provision of medical supplies, durable medical equipment, and drugs necessary for the palliation of pain and symptoms associated with the terminal illness and related conditions. In addition, the written agreement would delineate all other hospice services that would be necessary for the care of the resident's terminal illness and related conditions.

Comment: Several commenters had concerns with the lack of clarity as to whether the LTC facility or the hospice provider would take the lead as the primary decision maker. Two commenters suggested that the attending physician maintain oversight of care of the resident and ensure that the care providers are in compliance with the documented plan in the patient's medical record. One commenter also stated that the hospice medical director should serve as a consultant and advisor to correct problems with the delivery of hospice services by LTC facility personnel. Another commenter suggested that only one physician should approve or disapprove all documented orders for patient care and that doctor must be credentialed in the LTC facility.

Response: There is no Federal regulation precluding the LTC staff from taking orders for care from the hospice physician regarding a resident's terminal illness and related condition. The written agreement should identify how the LTC staff communicate and receive orders from the hospice physician in relation to the terminal care.

The hospice regulations at §418.112(c)(3) through §418.112(c)(7) describe the role of the hospice in caring for an LTC resident. The hospice is responsible for all decisions related to the care provided for the terminal illness and related conditions. The LTC facility maintains responsibility for all other care decisions. In accordance with the requirements at §418.56(c)(2), hospices are responsible for communicating with the patient/resident, family members, and attending physician at all points during the decision-making process to develop and update the content of the hospice plan of care. The hospice medical director, as the individual responsible for the medical component of the hospice's patient care program, is available to provide expertise in all necessary cases.

In addition, hospices are required to provide physician services (§418.64(a)) in conjunction with the patient's attending physician to manage the patient's hospice care and to provide additional non-hospice physician services when the patient's attending physician is not available. Therefore, we believe care coordination is explicit in the regulation.

Comment: One commenter suggested that the reference to "all other hospice services that are necessary..." in §483.75(r)(2)(ii)(H) of the proposed rule should be elaborated to include 'home health aide/nursing assistant services and therapy.' The commenter noted that these services have posed the biggest challenges regarding determination of responsibility. For example when the hospice plan of care has included placement of a home health aide/nursing assistant in the facility, the entities have been confused regarding their obligations for personal care.

Response: We understand the commenter's concern with the abbreviated list not including all possible services that the hospice would provide. We do not view those services not listed as less important, however, the list of services provided is an abbreviated list; we did not intend it to be all-inclusive. Hospice is responsible for providing all hospice services including the provision of hospice aide services, if these services are determined necessary by the Interdisciplinary Group (IDG) to supplement the nurse aide services provided by the facility. In entering into a written agreement with each other, each provider clearly delineates responsibilities for the quality and appropriateness of the care it provides in accordance with their respective laws and regulations. Both providers must comply with their applicable conditions or requirements for participation in the Medicare and/or Medicaid programs. The facility's services must be consistent with the plan of care developed in coordination with the hospice, and the facility must offer the same services to its residents

who have elected the hospice benefit as it furnishes to its residents who have not elected the hospice benefit. Therefore, the hospice patient residing in a facility should not experience any lack of services or personal care because of his or her status as a hospice patient.

Administration of Prescribed Therapies

We proposed 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 did not receive any comments on this proposal. Therefore, we are adopting it in this final rule without change.

Abuse

We proposed at §483.75(r)(2)(ii)(J) that the written agreement contain a provision 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.

Comment: One commenter believed that the proposed rule lacked direction in reporting alleged abuse and what the LTC facility's liability would be if the situation was not corrected and documented within the patient's records. The commenter suggested that the final rule require that a resolution process be documented in the patient's care plan, enabling those who are accountable for the care of the patient to be aware of their roles and responsibilities as well as increasing patient safety and improving quality of care.

Response: The written agreement specifies that the LTC facility must report alleged violations by hospice personnel to the hospice administrator immediately when the LTC

facility becomes aware of the alleged violation. This is to assure that the hospice administrator is not only aware of the alleged violation, but also begins an investigation as required in the hospice CoPs at §418.52(b)(4). We disagree with the commenter's suggestion regarding reporting alleged abuse in the resident's plan of care. The plan of care is a treatment plan that is developed according to the needs of the residents upon admission. Changes to the plan of care are made according to changes in the resident's condition and treatment needs. Moreover, the LTC facility must follow our regulations at §483.13(c), "Staff Treatment of Residents," which require the facility to protect its residents from abuse; to identify, investigate, and report any alleged violations; and to take appropriate corrective action. Additionally, §483.13(c) currently includes requirements for abuse documentation; therefore it would be duplicative to include an additional requirement in this final rule.

Bereavement Services

We proposed at §483.75(r)(2)(ii)(K) that the agreement also include a delineation of the responsibilities of the hospice and the LTC facility to provide bereavement services to LTC facility staff.

Comment: Several commenters had concerns with this requirement in the proposed rule. One commenter suggested that the requirement should be removed, stating that the hospice agency should not be held responsible for providing bereavement counseling for LTC facility staff. It was suggested instead that LTC facilities should be held responsible for providing bereavement counseling for their own staff members. A few commenters requested additional information to be added regarding the duration and location of the services and whether one-on-one or group services would be acceptable. Additionally, commenters requested information clarifying which hospice would be responsible for

providing the services in an LTC facility in the event that the facility contracts with more than one hospice for services.

Response: We understand the concerns expressed by the commenter regarding the removal of the bereavement requirement for hospices. However, this requirement is consistent with hospice requirements at §418.112(c)(9) and changes to the hospice regulations are beyond the scope of this regulation. The agreement between the hospice and the LTC facility should detail how the services will be coordinated and provided by the hospice provider for the LTC staff. The bereavement services are based upon the relationship between the care provider and the hospice resident. The hospice and the LTC facility should collaborate and communicate in order to determine which LTC staff will benefit from the bereavement services. In the cases of several hospices offering services in a facility, the individual hospice and the facility, as noted above, should review and identify those LTC staff who will benefit from the bereavement services. This should be individualized based on the resident involved and the staff involvement in their care. The agreement will identify how this service will be implemented by the certified hospice. Since the proposed language reflects the requirement already in hospice CoPs, we are not making any changes to the current language. Rather, we believe it should stay consistent with the current hospice regulation at §418.112(c)(9).

Interdisciplinary Team Member

At §483.75(r)(3)(i) through (v), we proposed that the LTC facility that arranges for the provision of hospice care under 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 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 including the most recent hospice plan of care specific to each patient; hospice election form; 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 provides 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.

Comment: The majority of the commenters supported the requirement designating a member of the LTC facility's interdisciplinary team to be responsible for working with hospice representatives to facilitate the coordination of care. A few commenters however, were unsure if the designation of the facility's interdisciplinary team member required a specific person by name or designation of a specified staff position and/or discipline. One commenter suggested the final rule specify the LTC representative be someone with a

clinical background, possibly a registered nurse (RN), as well as credentialed in the nursing facility.

Response: We agree with commenters that the LTC representative should be an employee of the facility with a clinical background. However, we do not want to limit LTC facilities' clinical personnel options solely to a professional registered nurse. The responsibilities of the interdisciplinary team member could be fulfilled by other clinicians participating in the care of the resident. We believe that by limiting the interdisciplinary team member to only a registered nurse, staffing issues may arise in addition to the possibility of increasing burden on the facility. In light of the complex clinical needs of a resident who is in the terminal stages of life, we believe it would be beneficial for the interdisciplinary team member to have the ability to assess the resident or have access to someone that has the ability to assess the resident. We are not requiring the person assessing the resident to be on the LTC facility staff: for example, it could be the hospice RN that is required to be available 24 hours. Therefore, we have revised the regulation at §483.75(t)(3) to clarify that the LTC representative must have a clinical background, function within their State scope of practice act, and have the ability to assess the resident or have access to someone that has the skills and capabilities to assess the resident.

Comment: One commenter requested additional information regarding how a hospice program can best incorporate the LTC interdisciplinary member into the IDG. This commenter also wanted to know if this requirement would mandate that the interdisciplinary member directly participate in the hospice IDG meetings.

Response: In accordance with §418.56(d), the hospice interdisciplinary group is required to update the hospice plan of care no less frequently than every 15 calendar days.

The hospice interdisciplinary group must include specified core members; however, it is not limited to those core members. Rather, it is our expectation that all licensed professionals who participate in a patient's care will give input to the interdisciplinary group (§418.62(b)). Furthermore, the hospice is required to have a system of communication that ensures the ongoing sharing of information with non-hospice providers that are caring for a patient (§418.56(e)(5)). Finally, the hospice is specifically required to designate an individual from each interdisciplinary group that is responsible for a patient that resides in an LTC facility to act as a communicator and coordinator with the LTC representatives. In addition, the LTC facility is specifically required to designate an individual to coordinate with the hospice representatives. The regulation doesn't stipulate that the facility staff coordinator directly participate in the hospice care planning meeting, but it does not preclude them from attending. The LTC facility and hospice must work out the arrangements on how needed information for care planning and the delivery of care and services will be coordinated and provided based upon the needs of the resident.

Comment: One commenter has expressed concern with the requirement of the LTC facility interdisciplinary team member obtaining hospice medication information specific to each patient. An LTC pharmacy may experience difficulty with billing hospice medications to the correct payer without the appropriate notification by either the hospice provider or the LTC facility. This includes information as to whether the medication is "related to" the terminal illness, and the patient's insurance information. Because payment for medications not related to the terminal illness is the responsibility of the hospice patient or secondary payer, it is critical for the LTC pharmacy to have correct information. Generally, when an LTC facility resident elects hospice care, the LTC facility will typically have more

information on the patient's secondary insurance coverage. Because the hospice provider may not know the pharmacy contact information for each resident, it is only logical that notification by the LTC facility to the pharmacy seems most appropriate. Having specific regulatory language that would make the LTC facility aware of this requirement is needed to avoid the potential for inappropriate billing. The commenter recommends that the LTC facility be responsible for obtaining medication information from the hospice, and that the notification be communicated among the hospice provider, the LTC facility, and the pharmacy within 1 business day of any admission, discharge or any change in the patient's medications or payer status.

Response: We agree with the commenter that it is the responsibility of the LTC facility to obtain medication information from the hospice provider, and we believe that this concern has already been addressed in the regulations (see §483.75(t)(3)(iv)(F)). Further, §483.75(t)(3)(iv) clarifies what information the designated member of the LTC facility's interdisciplinary team is responsible for obtaining from the hospice provider, including, medication information as set out at §483.75(t)(3)(iv)(F)). Also, we expect that the LTC facility's designated member of the interdisciplinary team would appropriately communicate medication information and would identify the payer source for a resident before a change in their medical condition.

After carefully considering how resident information is communicated between the hospice and the LTC providers, we are making a change in the regulations text at §483.75(t)(3)(iii) regarding who is responsible for communicating with the hospice about, among other things, the resident's medication orders. We are replacing the phrase, "other physicians" with "other practitioners" to encompass all other non-physician personnel such

as an advanced practice registered nurse (APRN), licensed therapist, or pharmacist, in accordance with State law and scope of practice participating in the provision of care to the patient. We believe that this will address the commenter's concerns.

Comment: The majority of commenters agreed with the requirement that the LTC facility provide a written overview for orientation on the policies and procedures of the facility to hospice staff furnishing care to LTC residents. One commenter suggested that the information be standardized and readily available in electronic format throughout all facilities in order for hospice staff to have access to quick and concise training. Another commenter suggested the overview address high priority regulatory and care related issues including facility layout with a tour of the facility, abuse and/or neglect prohibition and reporting policies and procedures, fire safety, infection control, falls prevention, and internal communications processes. Another commenter suggested that the facility-based orientation overview should be reviewed and signed by hospice staff before provision of care and services to residents electing the hospice benefit. A commenter also suggested that a list of the services the facility would anticipate from the hospice would also help in focusing the orientation.

Response: We appreciate the suggestion offered by the commenter regarding a standardized electronic format to facilitate training of hospice staff. This regulation does not preclude LTC facilities from using a standardized electronic format for their hospice orientation. Therefore, we believe that the proposed language at §483.75(t)(3)(v) provides enough flexibility to LTC facilities that provide orientation to hospice providers on their policies and procedures. Although, we have not required all of the specific elements of an orientation, we expect that both the LTC facility and the hospice provider will ensure

appropriate orientation, including an outline of services that the hospice will provide, before the provision of care.

Comment: One commenter stated that cross orientation would increase the quality of patient care, therefore, it was suggested that language from the hospice regulation at §418.112 be added to the proposed rule to ensure that LTC staff furnishing care to hospice patients will also be oriented to the hospice procedures and policies.

Response: The regulations for the written agreements between the LTC facility and a hospice provide for orientation from the perspective of each entity. The SNF/NF orientation is meant to address the overall facility environment including policies, rights, record keeping and forms requirements. The hospice regulations at §418.112(f) require hospices to assure that LTC facility staff are educated about the hospice philosophy, hospice policies and procedures, principles of death and dying, individual responses to death, hospice patient rights, and paperwork requirements. The orientation requirements, while separate regulations for both the LTC facility and Medicare Certified Hospice, should be a collaborative effort between the hospice and the LTC facility, to assure that the hospice employees provide services and care effectively in the LTC facility and that the hospice ensures that the LTC facility staff understands the basic philosophy and principles of hospice care. We believe that the requirement at §483.75(t)(4)(v) is sufficient; therefore, we are finalizing this requirement as proposed.

Plan of Care

At §483.75(r)(4), we proposed that each LTC facility providing hospice care under a written agreement 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).

Comment: Some commenters suggested that the regulation be changed to mirror the State Operations Manual (SOM) which states, “Highest practicable physical, mental, and psychosocial well-being is defined as the highest possible level of functioning and well-being, limited by the individual’s recognized pathology and normal aging process.”

Response: We do not agree that this regulation should include the language that mirrors the definition in the SOM. The interpretive guidelines in the SOM are subject to more frequent informal changes based on the regulatory text of a final rule. Therefore, we will not change the language in the regulation.

Comment: One commenter suggested deleting the requirement for LTC facilities to have the most recent hospice care plan in its possession. LTC facilities would not know when the hospice revised its care plan and would rely on hospice staff to provide the updated care plan. The LTC facility should not be held responsible for not having it in place. It should be the obligation and compliance requirement for hospice. Therefore, if hospice staff failed to provide the most current plan of care, the LTC facility would not be held responsible.

Response: At §418.112(e)(3)(i) of the hospice regulations, hospices are required to provide the LTC facility with the most recent hospice plan of care for each patient. To ensure that all care providers are performing their duties in accordance with the most recent plan, it is appropriate to require the LTC facility to include the most recent plan of care in its files. If an LTC facility has reason to believe that the plan of care in its possession is out of date, it is incumbent upon the LTC facility to seek out the most recent information. The intent of this

regulation is to ensure coordination of care between the hospice and LTC facility. We would expect, through this coordination that the LTC facility would always have the most current hospice plan of care.

Comment: While the majority of the commenters supported the written agreement, some commenters had concerns about the lack of clear regulatory direction regarding the responsibilities of the LTC facility and the hospice provider and requested clarification regarding the requirement for two plans of care. There was concern that medical errors that could result from a requirement for two plans of care for patients electing to use the hospice benefit along with the subsequent increase in possible transitions and transfer. Commenters believed that dividing medical care duties and services between two facilities will open the door for medical malpractice and further the chances for neglect of health care and safety and continue to exacerbate the lack of coordination between hospice and LTC providers.

Response: Having a written agreement that clearly delineates roles, responsibilities, expectations, and communication strategies should enhance, rather than impede, the coordination of care. This rule, when paired with the hospice regulatory requirements for written agreements, required services, and designated hospice representatives, will provide the overall structure for LTC-hospice relationships and written agreements. The hospice and LTC facility must collaborate to develop a coordinated plan of care for each patient that guides both providers. When a hospice patient is a resident of a facility, that patient's hospice plan of care must be established and maintained in consultation with representatives of the facility and the patient and/or family (to the extent possible). The hospice portion of the plan of care governs the actions of the hospice and describes the services that are needed to care for the patient. In addition, the coordinated plan of care must identify which provider

(hospice or facility) is responsible for performing a specific service. The coordinated plan of care may be divided into two portions, one of which is maintained by the facility and the other by the hospice. The facility is required to update its plan of care in accordance with any Federal, State or local laws and regulations governing the particular facility, just as hospices need to update their plans of care according to §418.56(d) of the CoPs. The hospice plan of care must specifically identify or delineate the provider responsible for each function, service, and intervention included in the plan of care. The providers must have a procedure that clearly outlines the chain of communication between the hospice and facility in the event a crisis or emergency develops, a change of condition occurs, and/or changes to the hospice portion of the plan of care are indicated.

III. Provisions of this Final Rule

We are adopting the provisions of this final rule as proposed, with the following changes:

- We originally proposed the standard regarding LTC facility/Hospice cooperation at §483.75(r); however, during the process of finalizing this rule, CMS published a separate interim final rule, Requirements for Long-Term Care (LTC) Facilities; Notice of Facility Closure (76 FR 9503). The interim final rule added standards §483.75(r) and (s). Since the standards at §483.75(r) and (s) are now in use, we are finalizing this standard at §483.75(t).
- In consideration of public comments, we are making three substantive changes in this final rule. We have made a revision at 483.75(t)(3) to clarify that the LTC representative must have a clinical background, function within their State scope of practice act, and have the ability to assess the resident or have access to someone that has the skills and capabilities to assess the resident. We have also made a revision to the requirement at §483.75(t)(3)(iii)

removing the phrase “other physicians” and replacing it with “other practitioners.” Lastly, we have made a revision to the requirement at §483.75(t)(2)(ii)(E)(3) by removing the phrase “that is not related to the terminal condition.”

Technical Correction

- We are finalizing the proposed technical correction which would fix an incorrect citation

at §483.10(n). In §483.10(n), we are revising the reference “§483.20(d)(2)(ii)” to read “§483.20(k)(2)(ii).”

- We are also finalizing the proposed technical correction which would fix an incorrect citation at proposed §483.75(r)(4). In §483.75(t)(4), we are revising the reference “483.20(k)” to read “483.25.”

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment 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 solicited 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) stated that if hospice care were to be provided in an LTC facility through an agreement with a Medicare-certified hospice, the LTC facility would have to have a written agreement with the Medicare-certified hospice before care was furnished to any resident.

An LTC facility will be required to have only one written agreement with each hospice that provides services in the facility. This final rule will 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 will require staff time; however, it will 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 for the 16,139 LTC facilities that would be affected by this rule. The current requirements at §483.75(h) “Use of Outside Resources,” requires a written agreement when contracting for outside services. Therefore, we expect that a facility will modify an existing agreement to make it specific to hospice services. Review and revision of an already existing agreement will be expected to take less time thereafter. We estimate that it will 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 §483.75(r)(2)(ii)(E)(1) through (4) stated that the LTC would have to 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 will take the LTC facility to provide notification to the hospice. We estimate it will take approximately 5 minutes per notification. We anticipate that this will affect 16,139 LTC facilities. If each LTC facility makes one notification each month, the burden associated with this requirement is 16,139 annual burden hours and the cost will 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) stated that under the agreement, the LTC facility would be required to 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 will take the LTC facility to report this information to the hospice administrator. We estimate it will take approximately 10 minutes per incident. We anticipate that this will affect 16,139 LTC facilities. If each LTC facility made one report per month, the burden associated with this requirement will 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.

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

Comment: A few commenters expressed concern about this rule creating additional administrative burden. One commenter was concerned that if the contracting process became too burdensome it could reduce beneficiary access to the critical services being requested.

Response: The burden associated with this requirement is the time and effort necessary to develop, draft, sign, and maintain the written agreement. The hospice regulations at §418.112 require hospices that provide services to LTC residents to have written agreements with LTC facilities. Furthermore, the regulations at §418.112 require

those written agreements to include specific provisions that are equivalent to the specific provisions that were proposed for LTC facilities. This requirement has been in place for hospices since December, 2008. Therefore, LTC facilities that currently have relationships with hospice providers should already have these written agreements in place. In addition, we believe the use of this type of written agreement is a usual and customary business practice, and therefore will not create additional burden on the facility.

Comment: Other commenters stated that the rule would save money by preventing double billing of services provided to the patients.

Response: We appreciate the support from commenters who recognized that this rule may save money by preventing double billing of services to the patients.

If you have comments on the reporting, recordkeeping or third-party disclosure requirements contained in this final rule, please submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, [CMS-3140-F]

Fax: (202) 395 6974; or

Email: OIRA_submission@omb.eop.gov

V. Regulatory Impact Analysis

A. Statement of Need

This final rule will revise the requirements that an institution will have to meet in order to qualify to participate as a SNF in the Medicare program, or as an NF in the Medicaid program. These requirements will ensure that LTC facilities that choose to arrange for the provision of hospice care through an agreement with one or more Medicare-certified hospice providers will have in place a written agreement with the hospice that specified the roles and

responsibilities of each entity.

Additionally, this rule will 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 requirements to the LTC regulations.

B. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). 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 entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that 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 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 will 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 Social Security 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 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 will impact only LTC facilities. Therefore, the Secretary has

determined that this proposed rule will 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 2011, that threshold is approximately \$136 million. This rule will 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.

C. 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, 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 LTC facilities and Medicare-certified hospice providers will be affected, as this rule will 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.

D. 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 will result in improvement in the quality of care provided to LTC residents receiving hospice services.

E. Conclusion

This rule sets out an LTC facility's responsibilities for developing a written agreement with a hospice if a resident elects to receive hospice care. This 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.

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

List of Subjects in 42 CFR Part 483

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

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR part 483 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, 11281, 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 (t) to read as follows:

§483.75 Administration.

* * * * *

(t) Hospice services. (1) A long-term care (LTC) facility may do either of the following:

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

(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 furnished in an LTC facility through an agreement as specified in paragraph (t)(1)(i) of this section with a hospice, the LTC facility must meet the following requirements:

(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 plan of care.

(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 about the following:

(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.

(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 appropriately based on the individual resident's needs.

(H) A delineation of the hospice's responsibilities, including but 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 appropriate 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 who is responsible for working with hospice representatives to coordinate care to the resident provided by the LTC facility staff and hospice staff. The interdisciplinary team member must have a clinical background, function within their State scope of practice act, and have the ability to assess the resident or have access to someone that has the skills and capabilities to assess the resident. The designated interdisciplinary team member is responsible for the following:

(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 practitioners 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.

(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.

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

(v) Ensuring that the LTC facility staff provides 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 §483.25.

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

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

Dated: December 7, 2012

Marilyn Tavenner,

Acting Administrator,

Centers for Medicare & Medicaid Services.

Approved: June 14, 2013

Kathleen Sebelius,

Secretary,

Department of Health and Human Services.

BILLING CODE 4120-01-P

[FR Doc. 2013-15313 Filed 06/26/2013 at 8:45 am; Publication Date: 06/27/2013]