DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 400, 405, 408, 409, 418, 420, 421, and 489

Medicare Program; Hospice Care

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed rule.

SUMMARY: These proposed regulations would implement section 122 of Pub. L. 97-248, the Tax Equity and Fiscal Responsibility Act of 1982, that provides coverage for hospice care for terminally ill Medicare beneficiaries who elect to receive care from a participating hospice. The regulations would establish eligibility requirements, covered services, reimbursement procedures, and the conditions a hospice must meet to be approved for participation in the Medicare program.

DATES: To assure consideration, comments must be received by September 21, 1983.

ADDRESS: Address comments in writing to: Health Care Financing Administration, U.S. Department of Health and Human Services, Rm. 132 East High Rise, Attention: BPP-241-P, 6325 Security Boulevard, Baltimore, Maryland 21207.

Please address a copy of comments on information collection requirements to: Office of Information and Regulatory Affairs, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, D.C. 20503, Attention: Desk Officer for HCFA.

If you prefer, you may deliver your comments to Room 309-G Hubert H. Humphrey Building, 200 Independence Ave., S.W., Washington, D.C., or to Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland.

Comments will be available for public inspection as they are received, beginning approximately three weeks after publication, in Room 309-G of the Department's offices at 200 Independence Ave., S.W., Washington, D.C. 20201, on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (202-245-7890).

FOR FURTHER INFORMATION CONTACT:

Coverage and Eligibility: Thomas Hoyer, (301) 594-9446.

Conditions of Participation: Samuel Kidder, (301) 597-5909.

Reimbursement: Bernard Truffer, (301) 597-1369.

SUPPLEMENTARY INFORMATION:

I. Background

Hospice care is an approach to treatment that recognizes that the impending death of an individual warrants a change in focus from curative care to palliative care.

The goal of hospice care is to help terminally ill individuals continue life with minimal disruption in normal activities while remaining in the home environment. A hospice uses an interdisciplinary approach to deliver medical, social, psychological, emotional, and spiritual services through the use of a broad spectrum of professional and other care-givers with the goal of making the individual as physically and emotionaly comfortable as possible.

The hospice experience in the United States has placed emphasis on home care. It offers physician services, specialized nursing services, and other forms of care in the home in order to enable the terminally ill individual to remain at home in the company of family and friends as long as possible. Inpatient hospice settings have been used primarily when there is no one in the individual's home to assist in his or her care, when the individual's pain and symptoms must be closely monitored in order to be controlled, or when the family needs a rest from the tedium and stress involved in caring for the individual (respite care).

Hospice care originated in Europe and has appeared in the United States only in the last ten years. A Joint Commission on Accreditation of Hospitals (JCAH) survey has identified more than 1200 organizations that consider themselves hospices in the United States. Coverage of hospice care as a separate mode of treatment was not included in the original Medicare legislation; however, many components of hospice care are covered by Medicare when furnished by a Medicare provider. For example, Medicare pays for home health services including various therapy services, the use of medical appliances and durable medical equipment; inpatient hospital services; and physician services. It does not pay for outpatient drugs or custodial care.

Because interest in the hospice movement has grown so rapidly, we began a demonstration project in October 1980 to study the feasibility of including hospice care as a Medicare benefit. The project has been funded for two years and has involved 26 demonstration hospice programs. We have used preliminary cost data from the demonstrations in developing the reimbursement methodology contained in this regulation.

As part of the Tax Equity and Fiscal Responsibility Act of 1982, Congress authorized hospice care as a new Medicare benefit

II. Legislative Amendments

Section 122 of the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982 (Pub. L. 97-248, enacted on September 3, 1982) expanded the scope of Medicare benefits by authorizing coverage for hospice care for terminally ill beneficiaries. Since Congress enacted this benefit with a "sunset" provision, the hospice benefit will be available only from November 1, 1983 through September 30, 1986 absent further legislation by Congress.

The principal changes enacted by section 122 of TEFRA that provide for hospice care are contained in sections 1812 (a)(4) and (d), 1813(a)(4), 1814 (a)(8) and (i), 1816(e)(5) and 1861(dd) of the Social Security Act (Act). Specific provisions of section 122 of TEFRA are described in Section III, Provisions of the Regulations.

III. Provisions of the Regulations

The law requires that we publish regulations to implement the hospice benefit by September 1, 1983. to meet this requirement, we plan to amend 42 CFR Chapter IV by revising Parts 400, 405, 408, 409, 420, 421, and 489 and by adding a new Part 418, Hospice Care. We would also make technical corrections to Parts 405, 421 and 489.

We would amend 42 CFR Part 409 at § 409.5 to include hospice care as a covered benefit under Medicare Part A in accordance with section 1812 of the Act. We would also make conforming changes to 42 CFR Parts 400, 408 and 420. Other revisions to Parts 405 and 421 and the provisions of the new Part 418 are discussed below. The discussions are arranged by topics and include the following: eligibility for hospice care, election and duration of the hospice benefit, hospice conditions of participation, covered services, hospice certification and provider agreements, reimbursement, beneficiary coinsurance, and designation of intermediaries.

A. Eligibility

The provisions specifying the requirements an individual must meet to be eligible to receive Medicare coverage of hospice care would be located in the new Part 418 of 42 CFR, within "Subpart B—Eligibility, Election and Duration of Benefits."

The regulations would use and define certain terms in accordance with section 1861(dd) of the Act. The proposed regulations define the term "terminally

ill" as having a medical prognosis that life expectancy is 6 months or less. The term "attending physician" means the physician who is identified by the individual as having the most significant role in the determination and delivery of medical care to the individual at the time he or she elects to receive hospice care. This physician may, but need not, be employed by the hospice.

The regulations would specify, consistent with the requirements of sections 1812 and 1814(a)(8) of the Act, that to be eligible for Medicare coverage of hospice care, an individual must be entitled to Medicare Part A, and must be certified as terminally ill.

Also in accordance with the Act at section 1812(a)(4), the proposed regulations specify that the hospice care benefit consists of two 90-day periods and one subsequent 30-day period which an individual may use in his or her lifetime. The proposed regulations refer to these periods as "election periods".

The proposed regulations reflect the certification requirements contained in section 1814(a)(8) of the Act. They require that for the first election period of 90 days, the individual be certified as terminally ill by his or her attending physician and by the medical director or physician member of the hospice interdisciplinary group. If the individual has no attending physician and is relying on the hospice to fill the major role in determining and delivering care, the regulations would require only one certification statement. This is consistent with the Congressional intent to help the individual avoid the need to find a second physician for the sole purpose of obtaining a certification statement (House Ways and Means Committee Print, "Explanation of H.R. 6878, The Medicare, Unemployment Compensation, and Public Assistance Amendments of 1982"). This certification would be made no later than 2 calendar days after hospice care is initiated. For the second 90-day or the subsequent 30-day period, the recertification of the terminal illness must be made by the medical director or physician member of the hospice interdisciplinary group.

The certifications and recertifications are statutory requirements for payment, and the regulations would therefore require that the hospice be responsible for obtaining the certification and recertification statements and for retaining them for verification (§ 418.22).

B. Election of the Hospice Benefit: Duration of Benefits

An individual who is eligible for coverage of hospice care is not automatically covered. Section 1812(d)(1) of the Act requires that the individual, in order to receive coverage of hospice care, must elect to receive that care from a particular hospice. In making this election, the individual also waives the right to payment for certain other benefits under Medicare.

To fulfill the requirements of section 1812(d)(1) of the Act, the proposed regulations at 42 CFR 418.24 would require the individual to complete an election form. Because an individual waives certain rights to payment in addition to choosing a palliative mode of treatment when hospice care is elected, we have not included any provision in the proposed regulations that would allow someone else, such as a legal guardian, to make an election on behalf of a beneficiary. We invite public comments on this issue.

The regulations would provide that the election form would be submitted through the hospice from which the individual elects to receive care before any services are provided. The hospice would immediately notify the intermediary so that the hospice could receive payment and the use of non-hospice services could be monitored by intermediaries and carriers. The individual would specify on the election form the date that the election period is to be effective. This date may be the first day of hospice care or any subsequent day of hospice care. The regulations would specify that an individual may not designate an effective date that is retroactive because a retroactive effective date would circumvent the required waiver of certain other Medicare benefits.

In accordance with section 1812(a)(4) of the Act, the regulations would specify that the two 90-day election periods must be used before the 30-day period. We anticipate that most individuals will use the election periods consecutively, that is, when one election period ends, the next will start immediately without a break in hospice care. Rather than require individuals to file an election form at the beginning of each election period, when an individual continues to receive hospice care, we would consider that the individual has elected to use election periods consecutively (without a break in hospice care). To end any election period and thus resume Medicare benefits waived, the individual must revoke the election of hospice care as described below.

The election form would need to indicate the individual's awareness that he or she is terminally ill. The individual's election would also constitute a waiver of certain other Medicare benefits. Section 1812(d)(2) of the Act provides that an individual, upon making an election to receive hospice coverage, would be deemed to have waived payments for certain other benefits except in "exceptional and unusual circumstances as the Secretary may provide." We have not specified any "exceptional or unusual circumstances" in the proposed regulations because we do not yet know of specific types of circumstances that may warrant the use of this exception. Comments on this point are invited.

To assure that an individual who elects to receive hospice care is aware of the benefits that the Act requires him or her to waive, the regulations would provide that the election form indicate the patient's understanding of the services to be waived. These services are:

- Hospice care provided by another hospice program (other than under arrangements made by the particular hospice program from which the individual elected to receive care).
- Any Medicare services that are related to the treatment of the terminal condition for which hospice care was elected or that are equivalent to hospice care. (Payment is not waived for services provided by the designated hospice or by another hospice under arrangements made by the designated hospice. In addition, payment is not waived for services provided by the individual's attending physician if that physician is not an employee of the hospice or receiving compensation from the hospice for those services (§418.24).)

Section 1812(d)(2) of the Act authorizes the Secretary to establish guidelines to stipulate what services are waived that are related to the treatment of terminal illness or are the equivalent of hospice care. We have not enumerated in this proposed rule the specific services that we consider related or equivalent to hospice care. We have not attmepted to enumerate the conditions for which care outside the hospice would be covered generally under Medicare because we recognize that there are many illnesses which may occur when an individual is terminally ill which are brought on by the underlying condition of the patient. For example, it is not unusual for a terminally ill patient to develop pneumonia or some other illness as a result of his or her weakened condition. Treatment of such illnesses is considered a hospice service and payment under other Medicare benefits is waived by the hospice election. There are also many services and procedures which may be used in curative treatment that may also be used for the

palliation of pain and symptom management. We expect that the hospice interdisciplinary group will reasonably determine the service that the individual requires for palliation and management of his or her symptoms.

To the extent that individuals seek and receive services outside the hospice program, Medicare coverage is determined by whether or not the services are for the treatment of a condition completely unrelated to the individual's terminal condition. As in the case of hospice services discussed above, we believe that this is a medical judgment which must be made on a case by case basis. Accordingly, Medicare fiscal intermediaries and carriers would make determinations in each case as to whether the services received are covered or are among the services waived through the hospice election. HCFA may issue guidelines from time to time as experience warrants.

As provided insection 1812(d)(2)(B) of the Act, the proposed regulations would permit an individual to revoke his or her election to receive hospice care at any time during an election period (§ 418.28). After revoking the election, the individual would no longer be entitled to coverage of hospice care for any days remaining in that period, and Medicare coverage would resume for those Medicare benefits previously waived. At any time after the revocation, the individual may elect to receive hospice care for a subsequent election period for which eligibility remains.

The regulations would provide that in order for an individual to revoke his or her election for hospice coverage, the individual would be required to submit a revocation statement to the hospice. This statement would declare the individual's intent to revoke the election and the date the revocation is to be effective.

The individual may not designate an effective date that is retroactive. Selection of a retroactive revocation date would circumvent the required waiver of other benefits.

Pursuant to section 1812(d)(2)(C) of the Act, the regulations would also provide that, once in each election period, an individual may change to another hospice program and the change would not be considered a revocation of the decision to receive hospice care for that particular election period (§ 418.30).

The regulations would provide procedures for the individual to change the designation of the particular hospice from which he or she elects to receive care. The individual would be required to prepare a change of election statement and file it with both hospice. The change of election statement would specify the date that the change is to be effective.

Consistent with section 122(h)(1) of TEFRA, the hospice benefit is available under Medicare only through September 30, 1986. The law also provides that an individual who has an election period in effect "on October 1, 1986" is entitled to continued hospice care coverage after that date for the remainder of that election period and any consecutive period to which the individual would have been entitled. Because the law specifies that the hospice benefit ends "before October 1, 1986", the regulations would provide that the individual who has an election period in effect "on September 30, 1986" is entitled to continued hospice care coverage (§ 418.32).

We recognize that further administrative procedures will need to be developed to enable this benefit to be implemented on a daily basis. There will need to be a mechanism by which the Medicare intermediary can learn that the beneficiary has elected hospice care so that: (1) Payments can be made to the hospice on a current basis, and (2) claims for out-of-hospice services by the beneficiaries can be identified and properly adjudicated. Hospices, too, will need to assure that they receive appropriate payments from intermediaries on a timely basis and that inappropriate payments are avoided. In addition, it will be necessary for the Medicare program to be informed of the beneficiary's most current choice (e.g., election, change, revocation, use of regular Medicare benefits) so that appropriate payments can be made to all providers.

We also recognize that there will be a need for checks and audits to assure that the hospice benefit is being provided and used as was intended by the law. We propose to closely monitor the incidence of hospice elections and revocations in connection with non-hospice Medicare admissions to hospitals to assure that manipulation and coercion do not take place. We also propose to set up a system of monitoring hospice care to assure that the needs of the patients have been met, that the billed-for services have been furnished, and that the other requirements for participation and payment are met.

C. Conditions of Participation

In accordance with section 1861(dd) of the Act, the regulations would define a "hospice" as a public agency or private organization or a part of either that is primarily engaged in providing specified services to terminally ill individuals and that meets certain specified conditions (§§ 418.50–418.100). Specific conditions are described in section 1861(dd) of the Act along with the provision that the Secretary may establish further conditions in the interest of the health and safety of individuals receiving hospice care. The regulations would establish conditions related to the following areas to be set forth in "Subpart C—Conditions of Participation" at 42 CFR Part 418.

1. General Provisions

As required by section 1861(dd)(2)(A), the regulations would specify that a hospice must be primarily engaged in providing the care and services listed in section III.C 3 and 4 of this preamble and bereavement counseling. These services must be available as needed on a 24-hour basis and provided in a manner consistent with accepted standards of practice. Care and services must be provided as necessary for the palliation and management of the terminal illness and related conditions (§ 418.50).

2. Administration

The regulations would specify that a hospice must meet the following conditions to ensure that quality care is provided and that fiscal and other responsibilities under the Medicare program are met.

a. *Governing body.* We would require the hospice to have a governing body that would provide for centralization of authority and responsibility for overall operation of the hospice (§ 418.52).

b. *Medical director.* We would also require the hospice to have a medical director to assume overall responsibility for patient care. This is based on section 1861(dd)(1) of the Act and is in support of sections 1814(a)(8) (A) and (B) of the Act that refer to the medical director's specific responsibilities for the certification of terminal illness and for establishing a plan of care for the individual (§ 418.54).

c. *Professional management.* Section 1861.(dd)(2)(A)(ii)(II) of the Act requires that the hospice must, if it arranges for another entity to furnish services to the hospice's patients, assure continuity of care and maintain professional management and financial responsibility for those services.

The proposed regulations would therefore require a legally binding written agreement between the provider of the services and the hospice. The regulations would specify that the arrangement must provide for continuing the plan of care established by the hospice interdisciplinary group and permit the maintenance of the hospice's medical records (§ 418.56). In addition,

the regulations would specify further requirements that would apply if inpatient care is provided under arrangements.

d. *Plan of care.* The proposed regulations would require that a detailed written plan of care be established and maintained for each individual receiving hospice care. This is in accordance with section 1861(dd)(2)(B)(ii) of the Act and is in support of section 1861(dd)(1), that requires that items and services provided as hospice care to an individual be provided under a plan of care (§ 418.58).

e. *Continuation of care.* We propose a standard of responsibility for the individual's care in accordance with section 1861(dd)(2)(D) of the Act that would specify that a hospice may not discontinue or diminish care provided to an individual because of the individual's inability to pay for that care. This provision would require a hospice to continue to provide care and services to any individual receiving care from the hospice. With respect to those individuals who are Medicare beneficiaries, this provision would require continuation of hospice services even after the individual exhausts the hospice benefits under Medicare as long as the individual continues to desire to receive the services and is terminally ill as defined in § 418.3 of the proposed regulations (§ 418.60).

f. *Informed consent.* We would require a hospice to demonstrate respect for an individual's rights. We believe that this would be achieved by ensuring that every individual has signed an informed consent form that specifies the type of care and services that may be provided as hospice care (§ 418.62). The consent form informs the individual of the hospice's patient care policies and responsibilities. The consent form could be combined with the individual's hospice election.

g. *In-service training.* We would require the hospice to provide an ongoing training program for hospice employees that is structured to ensure the quality of care (§ 418.64).

h. *Quality assurance.* We would also require a hospice to evaluate, on an ongoing basis, the quality of care provided. We believe that this evaluation would provide the information necessary for management to identify any problems that might jeopardize the quality of care. We would also require that the hospice correct any problems identified (§ 418.66).

i. *Interdisciplinary group.* We would require, in accordance with section 1861(dd)(2)(B) of the Act, that a hospice have an interdisciplinary group composed of at least a physician, a registered nurse, a social worker and a pastoral or other counselor. This group would be composed of paid hospice employees as well as hospice volunteers as long as the individuals in the group meet the appropriate qualifications. A hospice would need to meet three standards with respect to the interdisciplinary group: one regarding the composition of the group, another regarding the group's responsibilities for provision or supervision of care, and the third regarding the designation of a registered nurse to coordinate the overall plan of care for each patient (§ 418.68). We have specified that the coordinator must be a registered nurse because we believe that an understanding of the medical regimen being provided is essential, and that a registered nurse has the general knowledge required for the coordination of all other services being provided.

j. *Volunteers.* Congress recognized that the use of volunteers is fundamental to the hospice concept. The hospice benefit with the resulting Medicare reimbursement is not intended to diminish the voluntary spirit of hospices. Hospice volunteers offer a range of services from the provision of professional services to helping families with household chores, shopping or transportation. Section 1861(dd)(2)(E) of the Act requires that the hospice use volunteers to provide care and services in accordance with standards set by the Secretary. The statute further requires the maintenance of records on the use of volunteers, and the cost savings and expansion of care achieved through the use of volunteers. We believe that the intent of the law is that the Secretary should develop standards and monitor the level of volunteer activity to identify and forestall substantial diminution in the proportion of volunteer participation. Congressional intent (House Ways and Means Committee Print, "Explanation of H.R. 6878, The Medicare Unemployment Compensation, and Public Assistance Amendments of 1982") indicated that the Secretary would monitor the relationship of total volunteer hours to total enrolled days. We therefore propose standards regarding the role of volunteers; the recruiting, retaining and training of volunteers in order to ensure a continuing level of effort to use volunteers and standards relating to the documentation of volunteer activity (§ 418.70).

In addition, we are proposing a standard requiring hospices to make reasonable efforts to arrange for volunteer clergy and other members of religious organizations in the community to visit patients who desire such visits and to advise patients of this opportunity. Especially in light of the statutory requirement for counseling, we believe that this is an important use of volunteers.

We request that commenters share their experience and ideas on how we might accomplish the intent of the legislative mandate to ensure a continuing level of volunteer effort. Should a national or regional numerical standard be developed that would be applied to each hospice? If so, what measures should be adopted: A ratio of volunteer time to direct care time; a proportion of volunteers to enrolled individuals; a standard requiring a volunteer assigned to each patient; or another mechanism?

k. *Licensure.* As required by section 1861(dd)(2)(F) of the Act, we would require that a hospice be in compliance with applicable State and local licensure laws where they exist. We would also require that hospice employees be licensed, certified or registered in accordance with applicable State laws (§ 418.72).

l. *Central clinical records.* Section 1861(dd)(2)(C) of the Act requires that the hospice be required to maintain central clinical records for each individual receiving hospice care. We propose that a hospice meet standards relating to the content of the records and to protection of the records (§ 418.74).

3. Care Services

In accordance with section 1861(dd)(2)(A)(ii)(I) of the Act, the proposed regulations would require that nursing services, medical social services, physicans' services and counseling be routinely provided directly by hospice employees (§ 418.80). We would also propose conditions for the provision of these services.

Section 1861(dd)(2)(A)(ii)(I) specifies that a hospice "must routinely provide directly substantially all" of the core services. We believe that the distinction in the law and legislative history between those services that must be furnished directly and those that may be furnished under arrangements mandates that we define "directly" to require that services be provided by hospice employees. In a case where a hospice is a separately certified unit of another organization, our definition of "employee" would require that the individual is assigned and works substantially full time for the hospice unit. This requirement ensures that the core services are provided by employees "dedicated" to the hospice but would not preclude them from providing services outside the hospice unit. We

would define "employee" to include volunteers in order to encourage greater use of volunteers. We would allow the use of non-employee staff in situations of peak patient loads or in extraordinary circumstances.

We have also considered how the words "routinely" and "substantially" should be defined and believe that they should be construed to mean that the services provided directly by the hospice should be adequate to meet the needs of the hospice's average patient load. We believe that physician services, to meet this requirement, should be sufficient to meet the general needs of the hospice (e.g., medical director and interdisciplinary group member and general day-to-day, hands-on medical services required by hospice patients). Only physician services of a specialized nature (e.g., radiologists, anesthesiologists, and orthopedic surgeons) would appropriately be obtained under arrangements.

4. Other Services

As specified in section 1861(dd)(2) of the Act, the hospice would be required to provide, either directly or under arrangements, the following services when they are needed: physical therapy, occupational therapy and speech-language pathology; home health aide and homemaker services; medical supplies (including drugs and biologicals for palliation); and short term inpatient care. We would also set conditions for these services to ensure that the hospice maintains responsibility for the care and services provided. Specific provisions of the conditions regarding home health aide services and short term inpatient care are addressed below.

a. *Home health aides.* Section 1861(dd)(1)(D)(i) of the Act requires that a home health aide must have successfully completed a training program approved by the Secretary. Thus, the regulations would specify that a home health aide performing services in hospices must meet the training, attitude and skill requirements already specified in 42 CFR Part 405, "Subpart L—Conditions of Participation; Home Health Agencies" at § 405.1227.

b. *Limitation on short term inpatient care.* As required by section 1861(dd)(2)(A)(iii) of the Act, the regulations would include a condition relating to the use of short term inpatient care (§ 418.98). To participate in Medicare, the hospice would be required to ensure that the total number of inpatient days used by Medicare beneficiaries who elected hospice coverage in any 12-month period during the hospice's participation in the Medicare program did not exceed 20 percent of the total number of days of hospice coverage provided to those beneficiaries. Also, reimbursement to those hospices that exceed this percentage will be limited accordingly. We initially plan to accept as meeting this requirement the hospice's assurance that it will maintain the required ratio of inpatient to home care days. In subsequent surveys, however, evaluations of compliance will be based, to the extent possible, upon data relating to Medicare beneficiaries who have elected the hospice benefit. This condition reflects the statute's requirements governing the provision of *short term* inpatient care and the emphasis on the provision of care primarily in the home.

An exception to this limitation on the total number of inpatient care days is granted, in accordance with section 122(k) of TEFRA, to hospices that began operation before January 1, 1975. The exception would remain in effect until October 1, 1986.

5. Freestanding Hospices Providing Inpatient Care Directly

We would define a freestanding hospice as a hospice that is not part of any other type of participating provider. In order to ensure that basic requirements for the health and safety of its patients are met, we propose to establish standards for freestanding hospices that provide inpatient care directly. For this purpose, we have adopted many of the standards that already exist (at 42 CFR Part 442) for intermediate care facilities (§ 418.100). Freestanding hospices that meet the basic requirements may be approved for Medicare participation with respect to inpatient care under these standards.

D. Covered Services

We would include in the regulations a "Subpart D—Covered Services" at 42 CFR Part 418. In accordance with the statute at section 1861(dd)(1) of the Act, the regulations would list the services covered as hospice care as follows: nursing care; medical social services; physicians' services; counseling services (except for bereavement counseling); short term inpatient care; medical supplies (including drugs and biologicals, as defined in section 1861(t) of the Act, for palliation); services of home health aides and homemakers; and physical therapy, occupational therapy, and speech-language pathology.

The statute at section 1861(dd)(1)(B) of the Act specifically lists "physical or occupational therapy or speech-language pathology" as a covered hospice service. However, we do not believe that Congress, by use of the word "or", intended to limit coverage to only one of those services at a time. We have therefore specified in the proposed regulations that hospice care includes coverage of physical therapy, occupational therapy and speech-language pathology.

The proposed regulations contain concise definitions of the covered services. Under a retrospective, cost-based payment system, more detailed definitions would be necessary to enable us to adjudicate individual claims, which would also need more detail regarding the specific items and services provided. The prospective rates described in this regulation, however, are based on the presumption that services that have been provided are covered. Thus, the need for more detailed coverage rules and the administrative structure to apply them is avoided.

The regulations specify, consistent with section 1862(a) of the Act, that services can only be covered as hospice care if they are reasonable and necessary for the palliation or management of terminal illness (including related conditions). The regulations would also specify that in order for services to be covered as hospice care, the individual must elect coverage of hospice care, the hospice must establish a plan of care that includes the services to be provided, and the hospice must obtain the required physician certification of the terminal illness (§ 418.200). These provisions are consistent with sections 1812(d)(1) and 1814(a)(8) of the Act.

In accordance with section 1861(dd)(1) of the Act, the regulations would provide that nursing care, homemaker services and the services of a home health aide may be furnished on a 24-hour continuous basis during periods of crisis as necessary to maintain the individual at home. The regulations would define a period of crisis as a period in which the individual requires continuous care which is predominantly provided by a licensed nurse. Either home health aide or homemaker services or both may also be provided on a continuing basis. This care must be necessary to achieve palliation or management of acute medical symptoms (§ 418.204(a)).

Respite care, as enumerated insection 1861(dd)(1)(G) and specified in the proposed regulations, is care furnished to an individual in an inpatient setting in order to provide relief to family members or others caring for the individual. The regulations, consistent with the provisions at section 1861(dd)(1)(G) of the Act, would limit

coverage of respite care to periods of five consecutive days (§ 418.204(b)). The law provides and the regulations specify that an exception to the limitation on respite care days would be granted to hospices that began operation before January 1, 1975. This exception would remain in effect until October 1, 1986.

E. Approval of a Hospice Program and Provider Agreements

Section 1864(a) of the Act requires the use of State survey agencies to determine a hospice's compliance with the conditions of participation. We would therefore amend 42 CFR Part 405 at § 405.1901 to include hospices as providers that must be certified in accordance with procedures already established in Part 405, Subpart S, "Certification Procedure for Providers and Suppliers of Services."

Section 1861(dd)(4)(A) of the Act provides that any entity that desires Medicare approval as a hospice and that is already approved as a provider of services (other than a hospice) will be considered to have met any of the requirements for hospice approval that are the same as those for the other provider approval. We do not believe that new regulations are needed to address this provision. As a matter of economic efficiency, State survey agencies already follow this procedure for other types of dually certified providers.

Section 1861(dd)(4)(B) of the Act requires that an entity that is approved as both a hospice and another type of provider must have separate provider agreements under Section 1866 of the Act and must file separate cost reports. We would amend 42 CFR Part 489 at § 489.2 to include hospices as providers that must have an agreement with HCFA in accordance with provisions already established at Part 489, "Provider Agreements Under Medicare".

Under section 1865(a) of the Act, if the Secretary finds that a national accrediting body provides reasonable assurance that the conditions are met, the Secretary may treat an institution accredited by the body as meeting the Medicare conditions. This exception to the usual approval procedure is commonly referred to as extending "deemed status" to the provider.

We are aware that the Joint Commission on Accreditation of Hospitals (JCAH) is developing standards for hospices and plans to initiate a survey effort to determine compliance with those standards. The details of the survey have not been determined. It would be premature to make a decision on deeming hospices accredited by the JCAH or by any other accreditation program until a survey process is begun and we gain experience to assess the efficacy of enforcement. Because of the sunset provision of the hospice benefit, we believe that it may be preferable to use State Medicare surveys so that a more accurate report based upon the specific provisions of the hospice benefit may be given to Congress in the limited time provided.

In accordance with section 1866(b)(4) of the Act, the regulations would specify that if an agreement between the Secretary and a hospice is terminated, there would be no reimbursement for hospice care provided under a plan of care that is established on or after the effective date of termination. If the plan is established for an individual before the effective date of termination, there would be no reimbursement for services provided after the calendar year in which the termination is effective. These provisions would be located in 42 CFR 489.55.

F. Reimbursement

With respect to Medicare reimbursement for hospice care furnished to Medicare beneficiaries, section 1814(i)(1) of the Act provides broad authority for calculating the amount of Medicare reimbursement for hospice care. Specifically, the statute provides that:

> The amount paid to a hospice program with respect to hospice care for which payment may be made under this part shall be an amount equal to the costs which are reasonable and related to the cost of providing hospice care or which are based on such other tests of reasonableness as the Secretary may prescribe in regulations (including those authorized under section 1861(v)(1)(A)) * * *.

This section of the statute provides considerable discretion in designing a reimbursement method for hospice care. The statute also requires that the total Medicare payments made during a reporting period not exceed a "cap" that is based on a percentage of the average amount that Medicare paid for traditional care during the last six months of life for Medicare beneficiaries who died of cancer. Additionally, the statute requires the imposition of copayments on respite care, and on outpatient drugs and biologicals.

Our objective is to design a payment method that provides for efficient operation while minimizing administrative burdens on HCFA and the hospices. We considered, but decided not to propose, a retrospective reasonable cost reimbursement system for Medicare payment of hospice care. This option would have extended to hospices the Medicare reasonable cost reimbursement method generally used for payment to other types of providers. Under this approach, payments would be made on an interim basis as services are provided. At the end of a reporting period, the Medicare intermediary would determine, based on a comprehensive report filed by the hospice of actual cost and utilization, the actual reasonable cost incurred by the hospice for care provided to Medicare patients. The total of interim payments made during the reporting year would be compared to the reasonable cost determined by the intermediary and a final cost settlement would be made.

The major advantage of this approach is that the payment system could be designed generally, based on previous Medicare program experience. There would be no need to develop payment rates immediately, as would be the case with prospective reimbursement. However, neither the short term nor the long term implications of a retrospective cost reimbursement system are desirable. The disadvantages of retrospective cost reimbursement, both in terms of program costs and the incentives given to health care providers are widely recognized. There is a Congressional mandate for HCFA to develop prospective payment systems for various Part A benefits. Medicare patients may well comprise a substantial portion of hospice patients, and a Medicare retrospective reasonable cost reimbursement system would provide a significant disincentive for efficient operations and control of program costs. Finally, retrospective reasonable cost reimbursement also requires substantial administrative effort and cost on the part of both the hospices and HCFA in billing, cost report preparation and review, auditing, and conducting final settlements with each of the participating hospices. For these reasons, we believe that retrospective cost reimbursement is clearly an inappropriate approach.

We also considered and rejected a prepaid capitation approach to hospice reimbursement. Under this approach, ACFA would have calculated a fixed amount which would have been paid for each patient who elected to receive care from a hospice. Under a proposed capitation approach, the rate would be designed to include reimbursement for all care furnished to the patient, and would not vary by the length of the patient's enrollment in the hospice program or with the amount or intensity of services furnished by the hospice.

This approach, similar to the manner in which certain health maintenance organizations (HMOs) are compensated, would provide the maximum incentives for efficiency, since the hospice would be at risk for both utilization and length of stay. Moreover, in terms of administrative ease, capitation is advantageous over more fragmented approaches.

However, there are significant variations in both length of stay and differences in intensity and mix of services furnished to patients among hospices in the Medicare demonstration. These variations relate to both patient characteristics and hospice facility characteristics. In addition, the data would need to be more refined to construct a capitation model. These uncertainties preclude the development of a capitation rate at present. Moreover, we are concerned that because of the charateristics of capitation reimbursement, an incentive would be established for hospices to minimize the services furnished to Medicare patients. This could most easily be achieved by seeking out those patients whose death could be expected to occur in a very short time. Because savings in the hospice program could be expected only if hospice care is a substitute for traditional care, and not an addition to such care, the characteristics of capitation reimbursement would tend to dilute any potential program savings.

1. Proposed Payment Method

We are proposing to use a prospective cost-based payment methodology for hospice care which would permit payment rates to be responsive to both length of stay and intensity and mix of services. Under this proposed methodology, hospices would generally be paid one of several predetermihed rates for each day in which a Medicare beneficiary is under the care of the hospice. The rates would vary depending on the level of care furnished to the beneficiary. (See section III F. 2 below.) As proposed, total reimbursement to a hospice for care furnished to a Medicare beneficiary would vary not only by the length of the patient's coverage period in the hospice, but also by the characteristics of the services (with respect to intensity and site) furnished to the beneficiary. The hospice payment amount for each level of care would be determined by HCFA in accordance with the methodology described in section III. F. 3 of this preamble. Our intention in establishing these payment rates is to approximate, as closely as possible, the costs hospices incur in efficiently providing covered hospice care. Thus, the payment amounts represent estimates of the costs hospices will incur in efficiently providing covered care.

Section 1814(i)(1) of the Act specifies that reimbursement for hospice care may not include payment for bereavement counseling and that reimbursement may not be made for counseling services (including nutritional and dietary counseling) as separate services. Thus in calculating the payment rates for hospice care, we would exclude bereavement counseling. We would, however, take into account the cost of providing other counseling services in developing the payment rates for hospice care.

Section 1814(i)(2) of the Act provides for a limit or cap on total Medicare reimbursement to the hospice. Payment would continue to be made to the hospice throughout its reporting period for each day of care furnished; however, the intermediary will monitor payments to assure that total payments do not exceed the statutory cap. The hospice would be required to return to the program any payments that exceed the cap amount. Additional details on the application of this cap are provided in section III. F. 7 of this preamble.

2. Levels of Care

For each day that a Medicare beneficiary is under the care of a hospice, the hospice would be reimbursed an amount applicable to the type and intensity of the services furnished to the beneficiary for that day. For purposes of determining the amount of payment, we propose to establish four basic categories: i.e., routine home care; continuous home care; inpatient respite care; and general inpatient care. A predetermined rate will be established for all of the categories. A brief description of each level of hospice payment is as follows:

a. *Routine Home Care.* We would pay a hospice the routine home care rate for every day a patient is at home and under the care of the hospice (and not receiving continuous home care), regardless of the volume or intensity of the services provided on any given day. We know that there are currently some days when an individual may not require any service as well as some days when several visits may be required. In the home health based demonstration projects, there were approximately .97 visits per day. It could be argued that this payment method creates an incentive for the hospice to underserve patients in order to profit from the fixed daily rates. It has been suggested that this incentive could be eliminated if a system were adopted under which payment is made only on days when services are furnished and which is sensitive to the number and type of services furnished.

We recognize the disadvantage of the method we are proposing and know that there are arguments for the other method of payment. We believe, however, that the demonstration projects (in which hospices were paid on a cost basis and theoretically did not benefit from providing either too many or too few services) have shown that hospice patients require a sufficiently intensive level of home care so that there will be few days upon which services will not be required. Payment of an average rate for every day of routine home care permits the hospice to provide the needed care in the most efficient and convenient method possible without the need to deal with the various coverage and payment rules that would be required if a more detailed and service-oriented payment system were implemented. Conversely, if we adopted a system that made payment contingent upon the frequency and volume with which services were provided, an incentive might be created to provide unnecessary services to obtain income (e.g., to create income to support excess staff in cases where too many nurses or therapists were employed by the hospice).

Although we propose to adopt this policy, we are interested in comments about it and suggestions as to potential alternative policies which may be appropriate to deal with this issue. Comments should particularly address the issues of which unit of payment (per diem or per visit) is preferable and how under a "per visit" method a minimum hospice visit would be defined.

b. *Continuous Home Care.* The hospice would be paid at a continuous home care rate when, in order to maintain the terminally ill patient at home, nursing care is necessary on a continuous basis during periods of crisis. Either home health aide or homemaker services or both may also be provided, but the preponderance of care would need to be nursing care and care would have to be provided for a period of at least 8 hours before home care could be considered to fall within this category. We have established this threshold at 8 hours because the demonstration data indicate that when this type of care is furnished, it rarely occurs for periods of less than this duration.

We do not believe that it would be equitable to pay the hospice at the same rate for 8 hours of services as for 24 hours of services. Thus, we are proposing to divide the continuous home

care rate into three portions. The hospice would be paid a portion of the rate for each period (or partial period) of care provided. That is, the hospice would be paid: one-half of the rate when care is furnished for at least 8 hours and less than 16 hours a day; three fourths of the rate when care is furnished for at least 16 hours and less than 20 hours a day; and eleven-twelfths of the rate when continuous care is provided for 20 or more hours per day.

The continuous home care rate is intended only for periods of crisis where predominantly skilled continuous care is necessary to achieve palliation or management of the patient's acute medical symptoms, and only as necessary to maintain the patient at home.

c. *Inpatient Respite Care.* The hospice would be paid at the inpatient respite care rate for each day on which the beneficiary is in an approved inpatient facility and is receiving respite care. The inpatient respite rate would apply specifically to situations where the patient's family members or other persons caring for the patient need a short period of relief.

Inpatient respite care may be provided only on an intermittent, nonroutine, and occasional basis and may not be reimbursed for more than 5 days at a time.

Because patients admitted for the type of care described in this section are not in need of care as described in section d., below, we believe that the payment made for the care should reflect the fact that the care could appropriately be purchased in an SNF or ICF rather than in a more expensive setting. Thus we have proposed that the basic rate would be the same regardless of the type of facility in which care in furnished (i.e., freestanding hospice, hospital, SNF or ICF).

The inpatient respite care rate would be paid for the date of admission and for each subsequent inpatient day, except the day on which the patient is discharged. (The hospice would be paid at the appropriate home care rate for the discharge day.) The total payment to a hospice for inpatient respite care is subject to the limitation described in section III.F.5.a. of this preamble.

d. *General Inpatient Care.* Section 1861(dd)(1)(G) of the Act includes as covered hospice care, short-term inpatient care for pain control or management of acute and severe clinical problems which cannot be managed in other settings. Therefore, the hospice would be reimbursed for services furnished when the beneficiary is in an approved inpatient facility for the performance of complicated procedures necessary for pain control or acute or chronic symptom management. For example, payment at the inpatient rate would be made during situations when the patient's condition is such that it is no longer possible to maintain the patient at home. None of the other fixed payment rates (i.e., routine home care) would be applicable for a day on which the patient receives inpatient care. Section III.F.3.d. describes the methodology we propose to use for reimbursement of this care. The total payment to a hospice for inpatient care is subject to the limitation described in section III.F.5.a. of this preamble.

3. Determination of Rates

In general, the proposed prospective payment rates for hospice care have been derived from data obtained from the Medicare hospice demonstration project. In calculating the proposed amounts, we have relied on data concerning the kinds of services furnished by hospices, the cost of such services, and frequency with which such services were furnished to hospice patients. We have also included overhead costs such as maintenance, depreciation, general accounting, capital and other administrative costs in the calculation of the individual service components (for example, nursing or home health services) that compose the payment rates. The demonstration data will ultimately reflect the experience of more than 6,000 Medicare patients who received care from the demonstration hospices during the course of the demonstration.

In proposing these payment amounts, we would point out that the demonstration data have not been finalized and that there are at least two factors which could alter the amount of payment. First, since patient-based data are not entered into the data files until three months after the patient has died, the data do not reflect the experience of all patients who received hospice care during the course of the demonstration. We have, however, received the data from the majority of the patients included in the study and preliminary indications are that the data base will not change significantly as the data from the remaining patients are included in it. Secondly, the cost data used in the proposed rates are calculated from the cost reports from the 26 demonstration hospices. These reports are in the process of being audited to assure that the reported costs are consistent with general Medicare reimbursement principles. In the final regulation, we will include cost data from the audited cost reports, and it is possible that the audit results may affect the cost data. However, the cost reports have already undergone a preliminary audit known as desk-review, and we do not believe that the formal audits will result in substantial changes in the cost data they reflect. The final regulation will, of course, incorporate any changes in the payment amounts which are necessitated by the audit results.

a. *Routine Home Care Rate.* As specified in § 418.302(d)(3) of the proposed regulation, the payment rate for routine home care would be paid to the hospice for each day during which a Medicare beneficiary is under the care of the hospice, and not receiving the care described in the other three categories.

In calculating the rate, we determined from the Medicare hospice demonstration data the types of services furnished by the hospices to Medicare patients on routine home care days, and the daily cost of each of these components. The rate for routine home care is the sum of the average daily cost of each of the service components. The average daily cost of nursing, home health, and social service/therapy services were calculated by the following process:

1. The average cost per visit for each demonstration hospice was calculated for each type of service. We then calculated the mean cost per visit for all hospices.

2. We then calculated the average number of visits for provision of these services received by hospice patients on routine home care days. We divided these figures by the average number of home care days to determine the average number of visits per day for each service type.

3. We multiplied the average cost per visit for each service (item 1) by the appropriate utilization component (item 2) to determine the average cost for each service per patient per day of routine home care.

With respect to the daily cost of drugs, supplies and medical equipment, we calculated the average cost per patient per day by calculating the average cost per patient for these items and dividing by the number of days of care. With respect to drugs, we reduced the daily cost by the applicable coinsurance amount (five percent), as specified in § 418.400(a) of the proposed regulation.

We also added a daily cost factor for the managerial expense of the hospice interdisciplinary group. The daily cost of the interdisciplinary group was calculated by dividing the average cost per patient for the group by the average number of days of hospice stay.

The following chart summarizes the calculation of the routine home care rate.

Service component	Average cost per visit	Average visits per day	Cost per day
Nursing	$61	.34	$20.74
Home Health	35	.46	16.10
Soc. Ser./Therapy	57	.08	4.56
Drugs (reduced 5% to reflect coinsurance			.95
Supplies			3.60
Equipment			.90
Interdisciplinary			6.32
Group			53.17

b. Continuous Home Care Rate. The proposed payment rate for continuous home care was calculated from Medicare hospice demonstration data on the cost of continuous home care. Using these data, we estimated the cost of providing continuous care for a 24-hour period, and divided the daily rate into three smaller intervals for billing purposes, as specified in § 418.302(d)(4) of the regulation. The reimbursement amount for each interval is based on the mean within each interval. While there may be some slight variations in the implied hourly rates at the margins of each bracket (for example, care rendered slightly over 8 hours implies an hourly rate of about $19, while care rendered slightly less than 16 hours implies an hourly rate of about $10), we anticipate a balancing effect. We rejected the alternative of using a flat hourly rate since this would create incentives to provide care longer while further complicating the billing system.

In calculating the daily rate, we multiplied the average hourly cost of continuous home care from the demonstration hospices ($12.12/hour by 24 hours to arrive at a daily cost of such care. To this amount, we added the daily cost of therapy visits, drugs, supplies and equipment, which were calculated specifically from the utilization of these services by demonstration patients who received continuous home care. We also included the average daily cost of the hospice interdisciplinary group.

The following chart shows the calculation of the continuous home care rate.

Service component	Average cost per visit (hours)	Average visits (hours per day)	Cost per day
Continuous care	$12.12	24 hrs.	290.88
Therapy	57.00	.06 visits	3.42
Daily cost of drugs (reduced 5% to reflect coinsurance).			2.00
Daily cost of supplies.			2.83
Daily cost of equipment.			6.51
Interdisciplinary group.			6.32
Continuous home care rate per Day.			311.96
8 up to 16 hour interval (⅓).			155.98
16 up to 20 hour interval (¾).			233.97
20 through 24 hour interval (1 ⅓₂₄).			285.96

c. *Inpatient Respite Rate.* The proposed rate for inpatient respite care was calculated using Medicare program data on the cost of routine skilled nursing facility (SNF) services. Experience under the hospice demonstration with inpatient respite care was extremely limited. Less than one percent of demonstration patients received care classified as inpatient respite care and use of the data from this small number of patients would be misleading. Since SNF services and even less expensive ICF services are widely available throughout the country, we would anticipate that hospices would have relatively little difficulty arranging for the availability of these services. We do not believe that payment of a separate rate for inpatient respite care furnished in a hospital is desirable because it would provide an incentive to furnish respite care in an unnecessarily costly setting. A hospice may provide inpatient respite care in any approved inpatient setting; however, Medicare payment would not exceed the inpatient respite rate.

We reduced the rate by the applicable coinsurance for inpatient respite care specified in the law and in section 416.400(b) of the regulations.

The rate calculations are as follows:

Service component	Cost per day
1982 mean routine cost per day for SNF	$44.85
Daily cost of supplies, drugs and interdisciplinary group (1981 hospice cost adjusted to 1982 by the medical component of the Consumer Price Index)	11.45
	56.00
Inflation adjustment (medical component of the Consumer Price Index from 6/82 to 4/84	X1.159
Subtotal	64.89
Less 5 percent coinsurance	−3.24
Inpatient Respite Rate	61.65

d. *General Inpatient Care.* As specified in § 418.302 of the proposed regulations, a hospice would be reimbursed for general inpatient care for pain control or acute or chronic symptom management. The cost of these services would be allowable only to the extent that the services are consistent with the plan of care established by the hospice interdisciplinary group.

We propose to establish a single rate to compensate hospices for general inpatient care. We are basing this rate on data collected in the hospice demonstration project for hospital-based hospices furnishing their own inpatient care because these organizations retained control over the care provided in the hospital hospice unit. We feel these costs (with appropriate adjustments) are indicative of the costs other hospices will incur in providing inpatient care in accordance with the statutory requirement that hospices retain professional management responsibility over all hospice care.

We know that much of the hospice-type inpatient care given now takes place in hospitals and virtually all the inpatient care provided in the HCFA demonstration projects took place in hospitals. Interviews with directors of hospices have indicated that hospice inpatient care requires a fairly service, intensive setting and a building that meets basic health and fire safety standards. Many hospices may choose to arrange for care with existing hospitals or skilled nursing facilities. Other hospices may prefer to establish discrete inpatient units on the premises of a hospital or skilled nursing facility or to establish a free-standing inpatient unit. We do not beleive that it is appropriate for us to shape the choices of a new hospice by stipulating the location in which the services are provided or by establishing different rates for different settings, because we believe that these actions could unduly affect the development of hospice inpatient care at a time when the Department cannot judge which of the possible alternative settings is the best. At the same time, we want to provide adequate funding for the level of inpatient services a hospice patient is likely to require so that quality inpatient care is available under the benefit. Finally, we want to establish a payment rate which is in line with the price of the Medicare program has establish for

comparable services under its other benefits.

In order to achieve this result, we have calculated an inpatient rate based on the routine and ancillary costs incurred during the demonstration project for hospital-based hospices. The routine component of this rate is adjusted to reflect national hospice inpatient routine operating costs (including capital). Based upon an examiniation of the regular Medicare cost reports for these hospital-based hospices, we found that, on the average, these hospitals' (non-hospice) routine operating costs exceeded national average routine operating costs by 29 percent. This can be attributed to the fact that most of these hospitals were teaching institutions located in higher cost urban areas. We have inferred that hospice routine operating costs in these same hospitals would also exceed the national average by 29 percent, and have adjusted that data to reflect this. We have added to this hospice routine cost an amount for ancillary costs which was also based on the average daily cost from demonstration data for hospital-based hospices. We then combined these two components (routine and ancillary) into one national hospice inpatient care rate, and updated this figure for inflation. The calculation is as follows:

Hospital based hospices' 1981 routine operating costs per day, from HCFA hospice demonstration (includes general and administrative overhead costs	$221
Ratio of non-hospice routine operating cost for hospice demonstration hospitals to national average routine operating costs	1.29
National hospice inpatient routine operating costs per day (1981)	$171
Hospice demonstration average ancillary cost per day—hospital based hospices (1981)	$45
National inpatient care rate from 1981 demonstration data	$216
1981 to 1984 increase in medical care expenditures—Consumer Price Index	X1.256
General Inpatient Care Rate	$271

A determination of final payment to the hospice for inpatient care will be made in accordance with section III. F. 5. a. of this preamble.

Summary of Payments

In summary, the proposed hospice payment rates are as follows:

1. Routine Home Care—$53.17 per day
2. Continuous Home Care:
   8 up to 16 hours—155.98
   16 up to 20 hours—233.97
   20 through 24 hours—285.96
3. Inpatient Respite Care—61.65 per day
4. General Inpatient Care—271.00 per day

While the prospective home care rates reflect the 1981 cost experience of demonstration hospices, we are not proposing to adjust or index these rates for inflation that will have occurred from 1981 to the date of implementation of hospice reimbursement.

This is due to the fact that we believe the rates are adequate, for the following reasons: The home care rates reflected in the demonstration included some overhead costs, such as data collection, that are not covered under this regulation. Since the hospices were reimbursed for costs and there were no tests of "reasonableness" applied, there were no incentives for efficiency. In addition, some hospices had a low volume of services with resulting higher costs per visit.

We are not proposing any specific mechanism to adjust the prospective rates after we begin to reimburse hospices. We will monitor the cost and utilization experience of participating hospices through the submission of cost reports filed by selected hospices as discussed in section III. F. 9 of this preamble. We intend to examine the payment rates closely and will adjust the rates as this experience dictates. If we revise the payment rates in the future, we will publish our proposals as a notice in the **Federal Register.**

4. Local Adjustment of Payment Rates

We are proposing to use a mechanism for local adjustment of the payment rates to reflect the differences from area to area in wage levels.

The local adjustment is necessary to permit payment of higher rates in areas with relatively high wage levels, and proportionately lower rates in areas with wage levels below the national average. We considered but rejected an approach using the level of Medicare expenditures nationally compared to locally to compute an index to reflect geographical differences in hospice costs. An index based on Medicare expenditures would be necessarily heavily weighted toward institutional costs and physician costs that would not be appropriate for hospices. Because hospice care is relatively labor intensive, we believe that a local adjustment based on wage differences would be more appropriate. This method is used in other areas of the Medicare program to adjust cost limits for regional differences.

To determine the adjustment to the payment rates, we are proposing to use the area wage index which is used by Medicare in establishing limits on hospital, skilled nursing facility and home health agency costs. An example of this index was published on September 30, 1982 (47 FR 43311).

This index relates the wage levels in each Standard Metropolitan Statistical Area (SMSA), New England County Metropolitan Area (NECMA) and rural area within a State to a national norm of 1.0. (This index is calculated based on data compiled by the Bureau of Labor Statistics and is updated annually. We plan to use the most recent index available in adjusting hospice payment rates and will include the latest index as an appendix to the final rule.)

In adjusting the payment rates, we propose to separate the national payment rates into components which reflect the estimated proportion of the rate attributable to wage and non-wage costs. We will adjust the wage component of each rate by the index applicable to the area in which the hospice is located. This procedure is known as weighting. The rate to be paid to a hospice will be the sum of the unadjusted non-wage component and the adjusted wage component. We do not propose to adjust the non-wage component of the rate since it is a relatively small component of the total rate and since no index appropriate for that purpose is available.

With respect to home care rates (routine and continuous), we propose to use the wage/non-wage proportions specified in Medicare's limit on home health agency costs. While it might be possible to develop a separate proportion specific to hospices, we believe that the hospice home care cost distribution should not differ substantially from that of home health agencies, and use of an index based on the cost of the latter is appropriate. However, if experience with hospice costs proves otherwise, we will develop a hospice-specific ratio.

With respect to inpatient respite care costs, we propose to use the wage/non-wage proportions specified in the cost limits on skilled nursing facilities. We believe this to be appropriate since these rates are based on general Medicare costs for these facilities. This approach is consistent with usual Medicare practice. We are proposing to subject only the portion of the general inpatient rates dealing with routine facility cost to the weighting procedure since the wage/non-wage proportion was derived from and applies specifically to the mean SNF cost per day ($51.98 as adjusted for inflation).

The following are the proposed wage/non-wage proportions for the hospice payment rates:

Rate	Wage component (percent)	Non-wage component (percent)
Routine home care	68.71	31.29
Continuous home care	68.71	31.29

Rate	Wage component (percent)	Non-wage component (percent)
Inpatient respite [1]	61.26	38.74
General inpatient care [2]	80.77	19.23

[1] Weighting applicable only to the SNF cost component, updated for inflation.
[2] Weighting applicable to the routine cost component ($214.76) only, after updating for inflation.

In calculating the amount of each rate to be adjusted, we will multiply the national rate by the appropriate proportion from the above table. However, in the case of the inpatient respite rate, this procedure is applied only to the SNF cost component after updating for inflation ($51.98). The other component of the rate is included in the unweighted component.

The following represents the amount (in dollars) of each rate subject to adjustment by the wage index.

	National rate	Wage component subject to index	Unweighted amount
Routine home care	$53.17	$36.53	$16.64
Continuous home care	311.96	214.35	97.61
Inpatient respite	61.65	31.84	29.81
General inpatient care	271.00	173.48	97.52

The following example illustrates how weighting would be accomplished for a hospice located in Baltimore, Maryland (wage index is 1.1352).

	National rate	Wage component subject to index	Index	Adjusted wage component	Non-wage	Adjusted rate
Routnie home care	$53.17	$36.53	1.1352	$41.47	$16.64	$58.11
Continuous home care	311.96	214.35	1.1352	243.33	97.61	340.94
Inpatient respite	61.65	31.84	1.1352	36.14	29.81	65.95
General inpatient care	271.00	173.48	1.1352	196.93	97.52	294.45

5. Limitation on Reimbursement

We are proposing to make payments to a hospice subject to a limitation on the number of days of inpatient care for Medicare patients.

a. Limitation on Maximum Number of Inpatient Care Days. The statute requires that the aggregate number of inpatient days (including general inpatient, and inpatient respite), during any 12 month period not exceed 20 percent of the aggregate number of days of hospice care provided to Medicare beneficiaries during that period. Accordingly, we are proposing a limit on the number of inpatient days for which payment will be made. The limitation will be applied at the end of the hospice "cap period" as described in section III. F. 7. d. of this preamble.

At the end of a "cap period", the limit on the maximum number of inpatient care days will be calculated based on 20 percent of the total number of days that Medicare patients were enrolled in the hospice. Interim payments made to the hospice for inpatient care will be compared to this limit as follows:

1. The maximum allowable number of inpatient days will be calculated by multiplying the total number of days of Medicare hospice care by 0.2.

2. If the total number of days of inpatient care furnished to Medicare hospice patients is less than or equal to the maximum, no adjustment will be necessary.

3. If the total number of days of inpatient care exceeded the maximum allowable number, the limitation will be determined by calculating a ratio of the maximum allowable days to the number of actual days of inpatient care, and multiplying this ratio by the total reimbursement for inpatient care (general inpatient and inpatient respite reimbursement) that was made. Any excess reimbursement will be refunded by the hospice. Overall payments to the hospice will be subject to the cap amount specified in section III.F.7 of this preamble.

b. *Application of Limits.* The limit on the number of inpatient days will be applied by the intermediary at the end of the "cap period", as described in section III.F.7.d. of this preamble. This procedure will be necessary to enable the intermediary to calculate the total payment to the hospice, prior to application of the hospice cap.

6. Adjustment for Physicians Services

With one exception, the basic payment rates for hospice care and payments for inpatient care which are described above are designed to reimburse the hospice for the costs of all covered services related to the treatment of the beneficiary's terminal illness. The data available to us do not enable us to develop an accurate prospective estimation of the cost a hospice incurs for professional services of physicians. However, the statute clearly includes physicians' services as a core service which must be substantially provided directly by the hospice. We have determined that these services cannot be incorporated into any of our models of services for determining the payment rates because they do not occur frequently or uniformly in the care of a typical hospice patient.

We are proposing, therefore, to reimburse the hospice separately (except as outlined below) for physicians' services that are furnished to hospice patients and that are provided by employees of, or under arrangements made by, the hospice.

Administrative and general supervisory activities performed by hospice physicians will not be reimbursed in this manner but will be accounted for in the calculation of the level of care rates. These activities would generally be performed by:

1. A physician acting in the capacity of the physician member of the hospice interdisciplinary group.

2. A physician acting in the capacity of the medical director.

The costs for these services are included in the reimbursement rates for routine home care, continuous home care, and inpatient respite care. The hospice would be paid for all other physicians' services that are furnished to individual patients and that are provided by hospice employees (excluding volunteers) or under arrangements made by the hospice, at 100 percent of the Medicare reasonable charge for the service. The hospice would bill these services to the Medicare carrier servicing the hospice. Total payments made to the hospice for these services would be counted, along with total payments made at the various hospice rates, in determining whether the hospice cap amount has been exceeded.

The services of a beneficiary's attending physician who is not an employee of, or receiving compensation from the hospice for the services provided for the hospice, would continue to be paid through the Medicare carrier at the usual Medicare rate of 80 percent of the reasonable charges. These services would not be counted in determining whether the hospice cap amount has been exceeded. This is because these services of an attending physician are not hospice care.

7. Hospice Cap

Section 1814(i) of the Act imposes an aggregate cap on Medicare payments to any hospice. The law prescribes in detail the method by which this cap will

be computed. Basically, the Secretary is required to determine (for the most recent year for which data are available) the average Medicare costs incurred for cancer patients during the last six months of life. This average cost is then to be updated for inflation using the Medical Care Component of the Consumer Price Index, and also to be adjusted for regional wage differences. The cap amount is set at 40 percent of that regional average figure. The total payment cap for any given hospice is established by multiplying the cap amount by the number of Medicare beneficiaries who received hospice services during the year. Under the law, the cap is an absolute limit on Medicare payments to a hospice. The methodology used to calculate the cap amount is described in further detail below.

Section 122(j) of TEFRA, as redesignated by § 309(a)(6) of the Technical Corrections Act of 1982 (Pub. L. 97-448), allows, and these regulations include, an exception to the application of this cap for hospices that began operation before January 1, 1975. These hospices are exempted from the cap until October 1, 1986, in order to ensure their continued viability.

a. *Base Period.* Section 1814(i)(2)(B)(v) of the Act specifies that, for purposes of determining the hospice reimbursement cap, ". . . the term 'base period' means the most recent period of 12 months (ending before the date proposed regulations are first issued to carry out this paragraph) for which the Secretary determines he has sufficient data to make the determinations required."

In order to calculate the hospice cap amount, we need complete payment data on services furnished to beneficiaries from a number of sources. We must include Medicare reimbursement made for inpatient hospital services, SNF care, home health services, physician services, outpatient hospital services, etc., all of which are generated from separate billing forms. The Medicare program routinely collects and aggregates this type of payment information for all covered services in its "Continuous Medicare History File". These data are gathered for a 5 percent sample of Medicare enrollees. However, this file is only complete through calendar year 1979. Therefore, even though we have more complete payment data for individual elements of Medicare reimbursement, such as physician charge screens or hospital reimbursement, we must use 1979 as the base year for purposes of calculating the hospice cap amount because it is the most recent year for which we have complete payment data for all elements of covered services. We do not believe that the use of 1979 as the base year would adversely affect the cap calculation, however, because the base year data would be adjusted for inflation as described in section III. F.7.d of this preamble.

b. *National Average Medicare Per Capita Expenditure.* Section 1814(i)(2)(B)(i) of the Act provides that the national average Medicare per capita expenditure amount be determined using Medicare records. The statute specifies that the calculation be made by determining (or estimating) the amount of Medicare payments made with respect to services furnished during the 6 months before death to those beneficiaries who died from cancer during the base period. These expenditures are to be divided by the number of beneficiaries identified to determine a national average.

The first step in this process is the identification of beneficiaries who died from cancer in calendar year 1979. HCFA's internal records do not include cause of death information for beneficiaries; however, they do include the principal hospital diagnosis for patients who had at least one hospital stay. From this data we can identify many patients who had a diagnosis of cancer, although the hospital diagnosis and the cause of death would not be the same in all cases. This method would, however, fail to identify those beneficiaries who died from cancer but were not admitted to hospital with this diagnosis. If the cap amount is computed exclusively on the basis of data on patients who have been admitted as inpatients of hospitals, the result could be to bias the national average upward since many beneficiaries who incurred lower costs and died of cancer without having been admitted as inpatients of hospitals would not be included in the calculation. If most cancer patients are hospitalized before death, the bias may not be significant. Nevertheless, we are exploring the possibility of identifying some of these beneficiaries by using an external source of information.

Cause of death information compiled from State death certificates is potentially available from records of the National Center for Health Statistics (NCHS). We are currently exploring the feasibility of obtaining the information from the NCHS. We believe that using NCHS data as a source of additional information does not violate the intent of the statutory provision (section 1814(i)(2)(B)(i) of the Act) which specifies the use of program data.

Once we have identified beneficiaries whose cause of death was cancer and who died in 1979, we will examine our utilization data to estimate the reimbursement for benefits provided to these individuals in the six-month period preceding death. Using these data, HCFA would establish a national average Medicare per capita expenditure for care furnished to these individuals.

c. *Regional Adjustments.* Section 1814(i)(2)(B)(iii) of the Act provides for an adjustment to the national average Medicare per capita expenditure to reflect relative differences between each region's average cost of delivering health care and the national average cost of delivering health care.

Presently, we are reviewing the available data and considering how we could differentiate between regions and index the regional cost of health care to the national average. We believe that the data will suggest natural groupings of cost that will permit us to divide the nation into regions on a State or sub-State basis. If we decide to use this approach, the average health care cost in each region (as determined from our data) would be compared to the national average health care cost to arrive at the regional adjustment.

As an alternative methodology for applying this regional index, we are also considering using the Bureau of Labor Statistics (BLS) wage index. This index reflects the different wage levels throughout the country. Since wages make up a large portion of a hospice's total costs, we believe that this would be a good indicator of the appropriate geographic adjustment factor. Moreover, we have used this index previously in making geographic adjustments in other aspects of the Medicare program; for example, in computing provider costs limits and in determining reimbursement rates for ambulatory surgical centers. If we decide to use the BLS wage index as the adjustment factor, we would define regions as the Standard Metropolitan Statistical Areas (SMSA) and other groups used by the BLS.

We do not intend to make a decision on which method of indexing we will use until late in the summer of 1983, because it will take several months to gather and analyze the data and to determine if they permit a satisfactory means of performing the adjustment. In the interim, we are soliciting public comments on both of these alternatives.

d. *Inflation Adjustment.* To determine the cap amount for each region for each cap year, the regional average Medicare per capita expenditure for that region for the base year (as determined in section c. above) is then adjusted for increases or decreases in medical care

expenditures. Section 1814(i)(2)(B)(iv) of the Act specifies that this adjustment shall reflect the percentage increase or decrease in the medical care expenditure category of the Consumer Price Index (CPI) for all urban consumers (U.S. city average), published by the BLS, for the fourth month of the base year to the fifth month of the accounting year.

While hospices would report cost and utilization data when requested by HCFA in accordance with their individual reporting years (§ 418.310(b) of this proposed regulation), it is not necessary to make the cap calculation specific to each hospice's fiscal reporting year. Rather, since the program will begin on November 1, 1983, we are proposing to calculate the cap for each hospice for a cap period beginning on November 1 and ending October 31. The total payment made for services furnished during this period would be compared to the cap for this period. This procedure should simplify the administration of this provision for both HCFA and the hospices.

Thus, the regional average amount will be adjusted to account for changes in the cost of medical care caused by changes in the economy between the base period and the fifth month (March) of the cap period. The hospice cap would also be adjusted in each subsequent reporting year to account for the economic impact of change in the cost of medical care. However, since the appropriate CPI factor would not be published by November of each year, hospices would not know the exact cap amount at the beginning of each reporting period.

e. *Number of Hospice Beneficiaries.* As specified by section 1814(i) of the Act, each individual hospice's cap amount is equal to 40 percent of the regional average amount, adjusted for inflation or deflation (as determined in accordance with subsections b through d above) multiplied by the number of Medicare patients who elected to receive care from the hospice in the reporting year. We estimate that the average cap amount per beneficiary for the first year of the hospice program will approximate $4232. This estimate was established by strict application of the requirements for determining the cap amount as contained in the legislation. The requirements do not allow discretion in the computation method. We used 1978 data as the basis for this estimate; however, we believe that 1979 data will be available by the time we publish final regulations. If so, we will use those data. The amount of the cap may vary somewhat based on the refinement of the data base that occurs between now and the issuance of final regulations and as a result of using the more recent 1979 data. Based on our experience, however, we do not believe that either of these factors will result in a significant variation in the cap amount per beneficiary, nor do we believe that a significant change in the cap amount could be accomplished without a change in the legislative requirements. (Note: We recognize that the estimated cap amount we have computed is significantly lower than the amount anticipated by the Congress at the time the legislation was passed. While we do not have legal discretion to modify the amount under current law, we understand that attempts are under way legislatively to modify the law and create a higher cap amount.)

The statute specifies that the number of Medicare patients used in the calculation is to be adjusted to reflect the portion of care provided in a previous or subsequent reporting year or in another hospice. With respect to the adjustment necessary to account for situations in which a beneficiary's election overlaps two accounting periods, we are proposing to count each beneficiary only in the reporting year in which the preponderance of the hospice care would be expected to be furnished rather than attempting to perform a proportional adjustment. Although section 1814(i)(2)(C) of the Act specifies that the cap amount is to be adjusted "to reflect the proportion of hospice care that each such individual was provided in a previous or subsequent accounting year * * *", such an adjustment would be difficult in that the proportion of the hospice stay occurring in any given year would not be known until the patient died or exhausted his or her hospice benefits. We believe that the proposed alternative of counting the beneficiary in the reporting period where the beneficiary used most of the days of covered hospice care will achieve the intent of the statute without being burdensome.

In determining at what point to include a beneficiary in calculating the hospice cap amount, we used the length of stay data collected through the Medicare hospice demonstration project. We found that the mean number of hospice benefit days during the demonstration equaled 44 days. Therefore, for purposes of calculating the payment cap, we are proposing that the hospice count beneficiaries who have filed an initial election to receive hospice care after October 9, which is less than 22 days before the end of the cap period, in the subsequent year. This figure represents half of the mean length of stay in the demonstration project. This method will produce a reasonable estimate of the proportionate number of beneficiaries to be counted in each cap period.

The cap will be calculated by including 40 percent of the full regional cap amount adjusted for inflation (as determined in section F. 7. d above) times the number of Medicare beneficiaries who:

(1) Have not previously been counted in either another hospice's cap or another reporting year, and

(2) Have filed an election with the hospice during the period beginning after October 8th of the previous year through October 8th of the current year.

Once a beneficiary has been included in the calculation of a hospice cap amount, he or she may not be included in the cap for that hospice again, even if the number of covered days in subsequent reporting period exceeds that of the period where the beneficiary was included. (This could occur when the beneficiary has breaks between periods of election.)

When a beneficiary elects to receive hospice benefits from two different hospices, we are proposing a proportional application of the cap amount. We believe it would be inequitable to count the patient's stay in the hospices as equivalent if there were marked differences in the length of stay in the two periods. Consequently, we propose to calculate the percentage of the patient's length of stay in each hospice relative to the total length of hospice stay. In this way, each hospice would be given credit for the appropriate portion for calculation of the cap amount.

We are aware that this type of apportioning of the benficiary's stay may result in the inclusion of a beneficiary in the calculation of the cap for a reporting period other than the period for which the services were furnished, since it is necessary that the beneficiary die or exhaust his or her benefits before the percentage can be determined. However, we believe that this proposal is the most equitable means of implementing the statutory direction to adjust the cap amount to reflect the proportion of care furnished under a plan of care established by another hospice program. Moreover, we expect that the situation of beneficiaries changing to other hospices would occur infrequently; thus, we do not anticipate that the effect on hospice payments would be significant.

B. Appeals

As stated above, the hospice would be paid at the appropriate rate for each day during a beneficiary"s election period plus 100 percent of the reasonable charge for physician services provided by physicians who are employees of the hospice, subject to the cap amount. A hospice that believes an error has been made in the determination of the amount of Medicare payments may appeal the determination. Since the normal administrative appeals process under section 1878 of the Act applies only to issues related to cost reimbursement, we are creating an appeals procedure that is comparable to the statutory procedure but that is not based on section 1878. For example, the hospice may appeal the intermediarey's determination as to which payment level is applicable for each day, or the intermediary's determination as to whether services provided outside the hospice program are related or unrelated to the terminal illness. The methods and standards for the calculation of the payment rates by HCFA would not be subject to an administrative appeal.

Hospice appeals of the computation of the payment limit or the amount due the hospice may be made when the amount in controversy is $1,000 or more. In this case, the hospice is entitled to a hearing by the intermediary. The hospice would present evidence to indicate that an error has been made in the calculations or that the intermediary did not apply the correct procedures in determining the amount of reimbursement. The hospice would also be permitted to appeal these issues to the Provider Reimbursement Review Board (PRRB) if the amount in controversy is $10,000 or more. The appeals process is set forth in 42 CFR Part 405, Subpart R. The intermediary or PRRB hearings are not appropriate for disputes involving the substance of the regulations or the law, such as the calculation of the payment amounts by HCFA.

Appeals of determinations on individual beneficiary claims may be made by the beneficiary in accordance with the procedures in Part 405, Subpart G. In these cases, the beneficiary may request a reconsideration regardless of the amount in controversy. If the beneficiary is dissatisfied with the reconsideration determination, he or she may appeal further by requesting a hearing if the amount in controversy is $100 or more. In accordance with Subpart G, the hospice also may appeal a finding by the intermediary that items or services furnished to a beneficiary are not covered because they are not reasonable and necessary for the palliation or management of terminal illness, and that the beneficiary or the hospice, or both, should have known this. The hospice may request reconsideration regardless of the amount in controversy. At least $100 must be in controversy to request a hearing. The hospice may not combine claims from more than one beneficiary to reach the $100 minimum.

9. Reporting and Recordkeeping Requirements

The prospective payment method we are proposing to use for hospice care enables us to design a system of reporting requirements which is less comprehensive than the requirements that are necessary to operate a retrospective cost based system.

HCFA is developing cost reporting forms and will distribute them upon completion to hospices so that they can make any changes needed in their recordkeeping systems to collect the necessary information.

G. Coinsurance

Section 1813(a)(4) of the Act specifies that the amount payable for hospice care shall be reduced by a coinsurance amount for drugs and biologicals provided on an outpatient basis, and for respite care. The statute further specifies in section 1813(a)(4)(B) of the Act that no coinsurance or deductibles, other than those permitted for drugs and biologicals and for respite care, may be imposed for services furnished by hospices to beneficiaries during the period of an election, regardless of the setting of the services. Hospices will be expected to charge beneficiaries for applicable coinsurance amounts.

We are not proposing to include the amount of coinsurance collected by the hospice in determining if the cap amount is exceeded. The statutory language specifies that "the amount of payment made under this part for hospice care . . . may not exceed the 'cap amount'. . .". Since the statute is specific regarding the amount of Medicare payment made, we are proposing to subject only actual payments made by the Medicare program to the cap amount. In this way, we also avoid additional administrative burdens associated with recordkeeping for drug coinsurance.

1. Drugs and Biologicals

The statute specifies that the hospice may charge the beneficiary a coinsurance amount equal to 5 percent of the reasonable cost of the drug or biological to the hospice, but not more than $5, for each prescription furnished on an outpatient basis. We have interpreted "furnished on an outpatient basis" to mean services that would be covered under the routine home care rate and the continuous home care rate. The statute further requires that the hospice establish a "drug copayment schedule" that specifies each drug and the copayment to be charged. The charges included on the schedule must approximate 5 percent of the cost of the drugs of biologicals to the hospice, up to the $5 maximum. Additionally, the cost of the drug or biological may not exceed what a prudent buyer would pay in similar circumstances. The intermediary will review the schedules developed by the hospices to assure that they are reasonable.

These schedules must be approved by the intermediary before they are used. The schedule will permit beneficiaries to know in advance the amount of copayment and will assure consistent assessment of copayments on beneficiaries. There is no cumulative maximum coinsurance for drugs and biologicals; therefore, the coinsurance is applicable for each prescription furnished by the hospice.

The statute specifies that the amount payable for hospice care shall be reduced by the copayment amount assessed the beneficiary. However, since we are proposing that the payment method used for hospice care furnished on an outpatient basis would be based on an all inclusive rate per day for the services furnished, we are also proposing that individual per diem payments not be reduced when the copayment for drugs is applicable. Instead, the application and collection of copayments by the hospice would be assumed and an adjustment would be made by HCFA in determining the payment rates for home care to offset the average copayment collected by the hospice. (See section III. F. 3 of this preamble for a description of the calculation of the rates.)

In developing the payment rates for routine home care and continuous home care, we propose to reduce the portion of the per deim rate attributable to drugs by the average coinsurance expected to be collected by the hospice before the rate is calculated. We have estimated the amount of offset from cost and utilization data collected from the Medicare hospice demonstration project. In addition to reflecting the intent of the statute more accurately, this proposed method of reducing Medicare payments by the coinsurance for drugs and biologicals would greatly simplify claims processing. If we were to reduce individual payments whenever a drug or biological was furnished by the

hospice to a beneficiary, the hospice would have to notify the intermediary through the billing process each time a drug was furnished, and indicate the number of drugs furnished during each visit. Under our proposed methodology this complication to the billing mechanism can be alleviated. Every outpatient visit would be billed and payment would be made uniformly at either the routine home care or continuous home care rate.

We are proposing this approach because we believe that this is the most equitable and least administratively burdensome means of implementing the copayment provision.

2. Respite Care

The statute specifies that the hospice may charge the beneficiary a coinsurance equal to 5 percent of the estimated cost of respite care. (See section III.F.3. of this preamble for a description of this estimate.) The total amount of coinsurance for respite care for any beneficiary during a hospice coinsurance period may not exceed the amount of the inpatient hospital deductible applicable for the year in which the hospice coinsurance period began. Section 1813(a)(4)(A)(ii) establishes a hospice coinsurance period for purposes of this provision as a period which begins with the first day for which an election for hospice services is in effect for the beneficiary, and ends with the close of the first period of 14 consecutive days on which no such election is in effect for the beneficiary.

Thus, if a beneficiary elects to use all 3 of his election periods consecutively (without a 2 week break), he or she would be subject to a maximum coinsurance for respite care equal to the hospital inpatient deductible. Similarly, if a break between election periods exceeds 14 days, the maximum coinsurance for respite care would double or triple (depending on the number of election periods used and the timing of subsequent elections).

Example: Mr. Brown elected an initial 90 day period of hospice care. Five days after the initial period of hospice care ended, Mr. Brown began another period of hospice care under a subsequent election.

Immediately after that period ended, he began a third period of hospice care under a final election period. Mr. Brown received inpatient respite care during all three periods of hospice care. Since these election periods were not separated by 14 consecutive days, they constitute a single hospice coinsurance period. Therefore, the maximum coinsurance for respite care during all three periods of hospice care may not exceed the amount of the inpatient hospital deductible for the year in which the first period began.

Because we wish to keep uniformity between application of the two types of coinsurance provisions, and because of the ease of administering the claims processing, we are proposing to reduce the payment rate for inpatient respite care determined by HCFA by the average amount of respite coinsurance expected to be collected, as we are proposing to do with the drug coinsurance. Thus, to establish the inpatient respite care rate, we would reduce the estimated cost of inpatient care by the projected average coinsurance amount.

The hospice is responsible for billing and collecting the coinsurance amounts from the beneficiary. We are not proposing a separate rate for respite care after an individual reaches the inpatient hospital deductible amount. It is highly unlikely that the beneficiary will exceed this limit on copayment. In order for this result to occur, more than 93 days of inpatient respite care would need to be received while he or she was under the care of the hospice. Section 1861(dd)(2)(A)(iii) of the Act limits inpatient days to 20 percent of the aggregate number of days of hospice care provided to Medicare beneficiaries and would be a deterrent to allowing an individual to receive 93 days of inpatient respite care. Section 1861(dd)(1)(G) of the Act, that limits respite care to periods of not more than 5 consecutive days, would also serve to reduce the possibility that an individual would receive 93 days of inpatient respite care. If the limit is reached, however, the hospice is prohibited by law from collecting additional copayments.

H. Intermediaries

Section 1816(e)(5) of the Act requires the Secretary to designate intermediaries to serve hospices. Therefore, we are proposing to designate one intermediary per State to serve freestanding hospices, except that certain designated intermediaries will serve freestanding hospices across State lines in keeping with their longstanding service area.

We believe that the designation of one intermediary per State to serve freestanding hospices would aid coordination between intermediaries designated to reimburse those hospices and the local intermediaries and carriers that would handle bills for services not related to the terminal diagnosis and services provided by an attending physician not employed by the hospice. This coordination will help to assure that appropriate payments are made for services provided to individuals electing hospice care.

Section 1816(e)(5) of the Act also directs the Secretary to give special consideration before designating an intermediary to serve a hospice if it is based in another Medicare provider (for example, a hospital or a home health agency). We have determined that a hospice that is a subdivision of another Medicare certified provider generally would be served by the intermediary serving the parent provider regardless of whether it is the designated hospice intermediary for the State. We believe that in many cases it will be the hospice intermedary.

We believe that having the same organization be responsible for payments to the parent provider and its subdivision certified as a hospice will provide necessary control of overall Medicare program payments to the facility. We believe that this consideration is sufficient to warrant some deviation from the statewide intermediaries that would be designated for freestanding hospices.

The one exception to a hospice being served by the same intermediary that serves its parent provider would be for a hospice whose parent provider deals directly with HCFA. The proposed regulations would require that these hospices use contract intermediaries designated by HCFA. This exception is based on our proposal, published in the **Federal Register** on February 18, 1982 (47 FR 7269), to reduce the number of providers dealing directly with HCFA. The requirement that hospices use contract intermediaries would prevent those hospices from having to change to another intermediary should the proposal to reduce the number of providers being served by HCFA be finalized.

The designation of statewide intermediaries to serve freestanding hospices and hospices whose parent providers are served by HCFA is consistent with HCFA's long-term goal for achieving an overall Medicare contractor configuration based on geography and workloads which meets program needs in a more efficient and effective manner. A similar regulation published in September 1982 designated statewide intermediaries to serve freestanding HHAs. Currently, in just over half of the States, only one intermediary is generally available to serve providers.

The crteria for selecting intermediaries to serve hospices would include past performance and the ability of the intermediary to assume the additional workload.

We propose that the following intermediaries be designated to serve

freestanding hospices and hospices whose parent providers are served by HCFA. We note that these designations are not final and may be changed. Except as noted below, each hospice that is required to use a designated intermediary would be serviced by the intermediary listed for its State.

Alabama—Blue Cross and Blue Shield of Alabama
Alaska—Blue Cross and Blue Shield of Washington and Alaska
Arizona—Aetna Life and Casualty
Arkansas—Arkansas Blue Cross and Blue Shield, Inc.
California—Blue Cross of California (Woodland Hills)
Colorado—Blue Cross/Blue Shield of Colorado
Connecticut—Blue Cross and Blue Shield of Connecticut, Inc.
Delaware—Blue Cross of Delaware
District of Columbia—Group Hospitalization, Inc. (Washington, D.C.)
Florida—Blue Cross and Blue Shield of Florida, Inc.
Georgia—Blue Cross of Georgia/Columbus, Inc.
Hawaii—Hawaii Medical Service Association
Idaho—Blue Cross of Idaho Health Services
Illinois—Health Care Service Corporation (Chicago, Ill.)
Indiana—Mutual Hospital Insurance, Inc. (Indianapolis, Inc.)
Iowa—Blue Cross of Iowa, Inc.
Kansas—Blue Cross of Kansas, Inc.
Kentucky—Blue Cross and Blue Shield of Kentucky, Inc.
Louisiana—Blue Cross of Lousiana
Maine—Associated Hospital Service of Maine
Maryland—Blue Cross of Maryland, Inc.
Massachusetts—Aetna Life and Casualty (Farmington)
Michigan—Blue Cross and Blue Shield of Michigan
Minnesota—Blue Cross of Minnesota
Mississippi—Blue Cross and Blue Shield of Mississippi, Inc.
Missouri—Blue Cross Hospital Services, Inc., of Missouri (St. Louis, Missouri)
Montana—Blue Cross of Montana
Nebraska—Mutual of Omaha Insurance Company
Nevada—Aetna Life and Casualty (Reno, Nevada)
New Hampshire—New Hampshire-Vermont Health Service, Inc.
New Jersey—The Prudential Insurance Company of America
New Mexico—New Mexico Blue Cross and Blue Shield, Inc.
New York—Blue Cross and Blue Shield of Greater New York
North Carolina—Blue Cross and Blue Shield of North Carolina
North Dakota—Blue Cross of North Dakota
Ohio—Hospital Care Corporation (Cincinnati, Ohio)
Oklahoma—Blue Cross and Blue Shield of Oklahoma
Oregon—Blue Cross of Oregon
Pennsylvania—Blue Cross of Greater Philadelphia
Puerto Rico—[To be designated]
Rhode Island—Hospital Service Corporation of Rhode Island
South Carolina—Blue Cross and Blue Shield of South Carolina
South Dakota—Blue Cross of Western Iowa and South Dakota
Tennessee—Blue Cross and Blue Shield of Tennessee (Chattanooga, Tennessee)
Texas—Group Hospital Service, Inc. (Dallas, Texas)
Utah—Blue Cross of Utah
Vermont—New Hampshire-Vermont Health Services, Inc.
Virgin Islands—[To be designated]
Virginia—Blue Cross of Southwestern Virginia (Roanoke, Virginia)
Washington—Blue Cross of Washington and Alaska
West Virginia—Blue Cross Hospital Services, Inc. (Charleston, West Virginia)
Wisconsin—Blue Cross/Blue Shield United of Wisconsin
Wyoming—Blue Cross of Wyoming

The following are the exceptions to the State designations:

- Group Hospitalization, Inc.—services of District of Columbia; Prince Georges and Montgomery Counties in Maryland; Arlington County, Fairfax County, and the cities of Alexandria, Falls Church and Fairfax in Virginia.
- Blue Cross of Western Iowa and South Dakota—services all of South Dakota and 26 counties in Iowa.
- Oregon Blue Cross—services Oregon and Clark County in Washington, a suburb of Portland.
- St. Louis Blue Cross—services Missouri, and Johnson and Wyandotte Counties in Kansas.
- Chattanooga Blue Cross—services Walker, Dade and Catoosa Counties in Georgia.

These service areas do not overlap with those of other designated intermediaries and thus are consistent with HCFA's plan for designating intermediaries to serve certain hospices.

The proposed designations of Medicare intermediaries to serve hospices require changes to 42 CFR Part 421, "Intermediaries and Carriers". Section 421.3 would be revised to insert the term hospices in the definitions of "Intermediary" and "Provider."

We are proposing to amend §§ 421.103, 421.104 and 421.106 to prohibit a hospice from electing, nominating or changing an intermediary as other providers are allowed to do. This limitation is contained in section 1816(e)(5) of the Act, which directs the Secretary to designate intermediaries to serve hospices "[n]otwithstanding any other provision of this title". The statute does not give hospices the option to choose an intermediary. We believe that hospices would be able to establish good working relationships with designated intermediaries. However, we recognize that problems may occasionally arise. HCFA regional offices would investigate these cases and make every reasonable effort to reconcile differences between the hospice and its intermediary. HCFA would review these problems as part of its responsibility to assure adequate contractor performance using the performance criteria included in current regulations at 42 CFR 421.120. HCFA would monitor the performance of all intermediaries on an ongoing basis to assure that designations remain appropriate.

These proposed intermediary designations for hospices would also require some changes to § 421.117. We are proposing to revise the title of § 421.117 to read "Designation of intermediaries for freestanding home health agencies and for hospices". That section would be revised to add a reference to section 1816(e)(5) of the Act that requires the Secretary to designate intermediaries for hospices. The revision would also specify that freestanding hospices and hospices whose parent providers are served by HCFA would receive payment for covered services furnished to Medicare beneficiaries through an intermediary designated by HCFA. Any other provider-based hospice would be served by the same intermediary that serves its parent provider.

IV. Impact analysis

A. Executive Order 12291

Executive Order 12291 requires Federal agencies to examine the economic effect of regulations that they issue to determine whether the effect meets any of the criteria of section 1(b) of the Order:

(1) Will have an annual effect on the economy of $100 million or more;

(2) Cause a major increase in costs or prices for consumers or individual industries; or,

(3) Cause significant adverse effects on competition, employment, investment productivity, innovation or on the ability of United States-based enterprises to compete with foreign based enterprises in domestic or export markets.

Currently, Medicare pays for many components of hospice care when furnished by a Medicare provider. Beneficiaries now receive home health care; durable medical equipment; inpatient hospital services; and physician services. Section 122 of TEFRA (Pub. L. 97-248) expands the scope of Medicare benefits by adding, for a 3-year period, under Part A, hospice care for terminally ill beneficiaries.

The estimated net costs of the hospice program are:

FY 84—$80 million
FY 85—$110 million
FY 86—$160 million

These net budget costs include the estimated payments to hospices offset by the "traditional care" hospital costs foregone.

HCFA actuaries reviewed the most current Medicare data for the last six months of life, for cancer deaths. The patterns of hospitalization and survival after the discovery of cancer were analyzed and matched to hospice stay duration distributions from the HCFA hospice demonstration. The analysis showed that even though persons dying of cancer used, on the average, close to 30 hospital and skilled nursing facility days in their last six months of life, there were less than ten cancer hospital days used after discharge from the stay in which cancer was initially diagnosed. It is unlikely that the hospital stay in which cancer is discovered would be shortened by the ability to choose hospice care, since it would take time following the initial cancer diagnosis for the cancer patient and his family to come to grips with the fact that the illness will be terminal and to identify and elect hospice care. Consequently, fewer than 10 hospital days would be replaced by hospice care for people who ultimately elect hospice, and persons receiving curative treatments during the stay would not elect hospice care. As a result it is anticipated that the average patient who elects hospice care will result in a net increase in Medicare program costs and these costs will increase as the number of beneficiaries who elect the hospice benefit increases.

Because of lack of actual program experience, we are not certain that this benefit is cost-beneficial to society as directed by section 2 of this Order. However, Congress has mandated this benefit, which we are implementing through these regulations, and the impact of which will be further analyzed during the benefit's 3-year duration.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (Pub. L. 96-354) requires Federal agencies to examine the anticipated impact of their regulations to determine whether they would result in significant impact on a substantial number of affected small entities. There are presently 1200 entities self-designated as hospices. Of these, 450 are hospital-based, 200 operate under the auspices of a home health agency (HHA) and 478 are independently operated. The remaining 72 self-designated hospices fall within a variety of other categories.

We are not able to determine the number of providers that would seek certification. We believe that those seeking certification would come from among the 1200 providers currently operating as self-designated hospices. This assumption results from the fact that:

(1) The incremental costs associated with meeting the proposed conditions of participation should not be prohibitive to these providers; and,

(2) Start-up costs for new providers aiming to become a hospice would not be reimbursed to the extent that they are under a cost reimbursement methodology. Currently operating self-designated hospices would not be affected by this point.

For those hospices that would seek certification, we believe that they would be affected by the conditions of participation, the proposed cap and the payment amounts.

1. Conditions of Participation

In order to determine any significant financial cost that the proposed conditions of participation may impose upon these hospice providers, we obtained estimates from reliable sources within national organizations representing hospice interests. They provided information on potential items and services hospices may not provide now, but would be required to provide in order to participate in the Medicare program. The information obtained reveals that hospitals and home health agencies (HHAs) may need to initiate or intensify bereavement and volunteer services before they will be eligible to participate as hospice providers.

The hospice concept, and consequently the proposed regulations, encourage volunteer use. Technically a hospice could have no salary costs, despite requirements for direct provision of physician, nursing, social work, and counseling services, if the hospice filled these positions with qualified volunteer professional specialists.

The costs associated with implementation of volunteer services should be negligible. We do not believe the recordkeeping requirements associated with volunteer use will represent a significant financial burden as many existing hospices keep records of volunteer use as a matter of practice.

Bereavement counseling, while not a reimbursable item is nevertheless a mandated service. Costs involved would depend upon the specialty of the bereavement counselor as well as whether or not this person serves in a volunteer capacity. Estimation of costs for bereavement counseling is totally speculative, since there has been no attempt on our part to specify the qualifications of a "counselor" or the time involved in bereavement counseling.

We have also identified the other specialty areas, i.e., social work, nursing and counseling that providers claim may have some impact on the costs associated with participation.

Hospices that offer social work services under contractual or consultative arrangements would be required to provide the services directly, by full-time or part-time employees. Since a consultant's hourly wage is more than that of a provider's employee, direct employment could prove to be in the facility's best financial interest.

Nursing services offered through contractual arrangements would also have to be realigned so that the hospice nursing employees are sufficient in number to meet the needs of the average patient census. Again, this could benefit the facility financially.

The third specialty area is counseling. (Bereavement counseling was addressed earlier.) Dietary counseling is already available and provided by hospitals and HHAs. Pastoral counseling, although available in hospitals but not necessarily in HHAs, is usually a volunteer effort. As in bereavement services, we have not required any specific occupational expertise for "other counselors".

Therefore, we do not foresee a financial burden placed upon a hospice provider for the required social work, nursing and counseling services. We further believe that any incremental costs imposed upon providers that want to participate as a hospice would not result in a significant impact.

2. Hospice Cap

The intention of the cap is to ensure that payments for hospice care would not exceed the amount that would have been spent by Medicare if the patient had been treated in a traditional setting. However, Medicare beneficiaries may use traditional forms of treatment before seeking hospice care. Therefore, although the cap places a limit on Medicare reimbursement for hospice care, based on the cost of traditional care, it does not assume that hospice care is used as a substitute for traditional care. As a result, despite the cap we project that Medicare costs overall would increase because of the addition of the hospice benefit.

We believe certified hospices would be impacted by the cap if: (1) their average length of stay is higher than the

experience with the demonstration; or, (2) if hospices' utilization of the more expensive levels of care (i.e., general inpatient care and continuous home care) is higher than the demonstration experience. However, the statute establishes the methodology for determining the cap amount which is described elsewhere in the preamble. Therefore, any impact on affected hospices would result from the statute and not these regulations.

3. Payment Amounts

The proposed payment amounts are intended to approximate the costs hospices generally incur in providing covered hospice care. In calculating these amounts, we have relied on data concerning the kinds of services furnished by hospices, the cost of such services and the frequency with which these services are furnished to hospice patients. The data received from our demonstrations reflect the experience of the demonstration hospices during the course of the demonstration. Therefore, we do not believe that the amounts would significantly impact on affected hospices as they approximate the current costs of operation and do not reflect a significant incremental change from the current situation.

For the reasons noted in this analysis, the Secretary certifies under 5 U.S.C. 605(b), enacted by the Regulatory Flexibility Act of 1980, that these proposed regulations are not likely to result in a significant impact on a substantial number of small entities.

C. Paperwork Burden

Sections 418.22; 418.56(d)(3), (5), and (7); 418.58; 418.70 (b), (c), and (d); 418.74; 418.96(a); 418.100(b); and 418.310 of this proposed rule contain information collection requirements. HCFA has submitted these requirements to the Office of Management and Budget (OMB) for its review under section 3504(h) of the Paperwork Reduction Act of 1980. Interested parties should direct their comments on the information collection requirements contained in this proposed rule to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for the Health Care Financing Administration.

V. Response to Comments

Because of the large number of comments we receive on proposed regulations, we cannot acknowledge or respond to them individually. However, in preparing the final rule, we will consider all comments and respond to them in the preamble to that rule.

List of Subjects

42 CFR Part 400

Health facilities, Health maintenance organizations (HMO), Medicaid, Medicare.

42 CFR Part 405

Administrative practice and procedure,
Certification of compliance,
Clinics,
Contracts (Agreements),
End-Stage Renal Disease (ESRD),
Health care,
Health facilities,
Health maintenance organizations (HMO),
Health professions,
Health suppliers,
Home health agencies,
Hospice care,
Hospitals,
Inpatients,
Kidney diseases,
Laboratories,
Medicare,
Nursing homes,
Onsite surveys,
Outpatient providers,
Reporting requirements,
Rural areas,
X-rays.

42 CFR Part 408

Health facilities,
Health maintenance organizations (HMO),
Kidney diseases,
Medicare.

42 CFR Part 409

Health facilities,
Health maintenance organizations (HMO),
Medicare.

42 CFR Part 418

Coinsurance,
Hospice,
Medicare,
Respite care,
Volunteers.

42 CFR Part 420

Administrative practice and procedure,
Fraud,
Health facilities,
Health maintenance organizations (HMO),
Health professions,
Medicare.

42 CFR Part 421

Administrative practice and procedure,
Contracts (Agreements),
Courts,
Health care,
Health facilities,
Health maintenance organizations (HMO),
Health professions,
Information (Disclosure),
Lawyer,
Medicare,
Professional Standards Review Organizations (PSRO),
Reporting requirements.

42 CFR Part 489

Clinics,
Comprehensive outpatient rehabilitation facilities (CORFs),
Health care,
Health facilities,
Hospices,
Medicare,
Provider Agreements,
Rural health clinics,
Termination procedures.

We are proposing to amend 42 CFR Chapter IV as set forth below:

A. The Table of Contents for Chapter IV is amended by adding a new Part 418 to Subchapter B to read as follows:

CHAPTER IV—HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

* * * * *

SUBCHAPTER B—MEDICARE PROGRAMS

* * * * *

Part 418—Hospice Care

* * * * *

PART 400—INTRODUCTION; DEFINITIONS

The authority citation for Part 400 reads as follows:

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

B. Part 400 is amended as follows:

Section 400.202 is amended by revising the definition of *"Provider"* to read as follows:

§ 400.202 Definitions specific to Medicare.

* * * * *

"Provider" means a hospital, a skilled nursing facility, a comprehensive outpatient rehabilitation facility, or a home health agency, or effective November 1, 1983 through September 30, 1986, a hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency, or a public health agency that has a similar agreement but only to furnish outpatient physical therapy or speech pathology services.

* * * * *

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Subpart C—Exclusions, Recovery of Overpayment, Liability of a Certifying Officer and Suspension of Payment

C. Part 405, Subpart C is amended as follows:

1. The authority citation for Subpart C is revised to read as follows:

Authority: Secs. 1102, 1128A, 1815, 1833, 1842, 1861, 1862, 1870, 1871 and 1879, Social Security Act as amended (42 U.S.C. 1302, 1320a–7a, 1395g, 1395l 1395u, 1395x, 1395y, 1395gg, 1395hh and 1395pp) and 31 U.S.C. 951.

2. Section 405.301 is amended by revising the introductory paragraph and paragraphs (g), (j) and (k) to read as follows:

§ 405.310 Types of expenses not covered.

Notwithstanding any other provisions of this part, or Part 418 of this chapter, no payment may be made for any expenses incurred for the following items or services:

* * * * *

(g) Custodial care except as necessary for the palliation or management of a terminal illness and related conditions as provided in Part 418 of this chapter (in the case of extended care services, any care which does not meet the definition of extended care in §§ 405.126–405.128);

* * * * *

(j) Personal comfort items and services (for example a television set, or telephone service, etc.) except as necessary for the palliation or management of a terminal illness and related conditions as provided in Part 418 of this chapter.

* * * * *

(k)(1) Which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (thus, payment could not be made for the rental of a special hospital bed to be used by an individual in his home if it was not a reasonable and necessary part of the individual's treatment); or,

(2) Which are not reasonable and necessary, in the case of hospice care provided under Part 418 of this chapter, for the palliation or management of a terminal illness and related conditions (thus payment may be made for hospice care that is reasonable and necessary for the palliation or management of a terminal illness and related conditions);

* * * * *

3. Section 405.330 is amended by revising the introductory material in paragraph (a) to read as follows:

§ 405.330 Payment for certain nonreimbursable expenses.

(a) Notwithstanding the provisions of § 405.310, payment may be made for items or services furnished after October 30, 1972, which involve custodial care (§ 405.310(g)); items or services which are not reasonable and necessary for the diagnosis or treatment of illness of injury or to improve the functioning of a malformed body member (§ 405.310(k) (1)); or, in the case of hospice care provided under Part 418 of this chapter, items and services which are not reasonable and necessary for the palliation or management of a terminal illness and related conditions (§ 405.310(k)(2)), If:

* * * * *

4. Section 405.332 is amended by revising the introductory material in paragraph (a) to read as follows:

§ 405.332 Criteria for determining that there was knowledge that certain items or services were excluded from coverage.

(a) *The individual to whom items or services are funished.* An individual shall be found to have known that items or services furnished to him were excluded from coverage only if he, or someone acting on his behalf, has been given written notice stating that the items or services were excluded from coverage. This paragraph applies only to items and services excluded from coverage as "custodial care" (§ 405.310(g)) or as "not reasonable and necessary" for the diagnosis or treatment of illness or injury or, in the case of hospice care provided under Part 418 of this chapter, for the palliation or management of a terminal illness and related conditions (§ 405.310(k)).

Written notice must consist of the following:

* * * * *

Subpart D—Principles of Reimbursement for Providers, Outpatient Maintenance Dialysis, and Services by Hospital-Based Physicians

The authority citation for Subpart D reads as follows:

Authority: Secs 1102. 1814(b), 1815(a), 1861(v), 1871, 1881, 1886, and 1887 of the Social Security Act as amended (42 U.S.C. 1302, 1395f(b), 1395(a), 1395x(v), 1395hh, 1395rr, 1395ww, and 1395xx).

D. Part 405, Subpart D is amended as follows: Section 405.455 is amended by revising paragraph (a) to specify that it does not apply to services furnished by hospices. As revised, paragraph (a) reads as follows:

§ 405.455 Amount of payments where customary charges for services furnished are less than reasonable cost.

(a) *Principle.* Providers of services, other than comprehensive outpatient rehabilitation facilities and hospices, will be paid the lesser of the reasonable cost of services furnished to beneficiaries or the customary charges made by the provider for the same services. (Payment to comprehensive outpatient rehabilitation facilities and hospices is based on the reasonable cost of services.) Public providers of service furnishing services free of charge or at a nominal charge will be paid fair compensation for services furnished to beneficiaries. This principle is applicable to services furnished by providers in cost reporting periods beginning after December 31, 1973. For special rules concerning HMO's and providers of services and other health care facilities that are owner or operated by an HMO, or related to an HMO by common ownerships or control, see §§ 405.2042(b)(14) and 405.2050(c).

* * * * *

E. Part 405, Subpart S is amended as follows:

1. The authority citation for Subpart S is revised to read as follows:

Authority: Secs. 1102, 1814, 1861, 1865, 1866, 1871, 1880, 1881 and 1883, Social Security Act as amended (42 U.S.C. 1302, 1395f, 1395x, 1395bb, 1395cc, 1395hh, 1395qq, 1395rr and 1395tt).

2. Section 405.1901 is amended by revising the introductory language in paragraph (a) and the definition of "Provider of services or provider", and by revising paragraph (b)(2) as follows:

§ 405.1901 The certification process.

(a) *Definitions.* As used in this subpart—

* * * * *

Provider of services or *provider* means a hospital, skilled nursing facility, home health agency, hospice, comprehensive outpatient rehabilitation facility, or provider of outpatient physical therapy or speech pathology services.

* * * * *

(b) *Conditions of Participation; Conditions for Coverage.*

* * * * *

(2) Be in compliance with the applicable conditions prescribed in Subparts J, K, L, M, N, Q, or U of this part, Subpart C of Part 41B, or Subpart A of Part 481.

PART 408—MEDICARE ELIGIBILITY AND ENTITLEMENT

The authority citation for Part 408 reads as follows:

Authority: Secs. 202 (t) and (u), 226, 226A, 1102, 1811 and 1818 of the Social Security Act (42 U.S.C. 402 (t) and (u), 426, 426–1, 1302, 1395c, 1395i–2. Section 103 of Pub. L. 89–97 (42 U.S.C. 426a)).

F. Part 408 is amended as follows: Section 408.2 is revised to read as follows:

§ 408.2 Scope.

This subpart specifies the conditions of eligibility for hospital insurance and sets forth certain specific conditions that affect entitlement to benefits. Hospital insurance is authorized under Part A of Title XVIII and is also referred to as Medicare Part A. It includes inpatient hospital care, posthospital skilled nursing facility care, posthospital home health services, and hospice care.

PART 409—MEDICARE BENEFITS, LIMITATIONS, AND EXCLUSIONS

The authority citation for Part 409 reads as follows:

Authority: Secs. 1102, 1812, 1813, 1814, 1861, 1866, 1871, 1881, and 1883 of the Social Security Act (42 U.S.C. 1302, 1395d, 1395e, 1395f, 1395x, 1395cc, 1395hh, 1395rr, and 1395tt).

G. Part 409 is amended as follows: Section 409.5 is revised to read as follows:

§ 409.5 General description of benefits.

Hospital insurance (Part A of Medicare) helps pay for inpatient hospital services and posthospital SNF care. It also pays for home health services and hospice care. There are limitations on the number of days of care that Medicare can pay for and there are deductible and coinsurance amounts for which the beneficiary is responsible. For each type of service, certain conditions must be met as specified in the pertinent sections of this subpart and in Part 418 of this chapter regarding hospice care. The special conditions for inpatient hospital services furnished by a qualified U.S., Canadian, or Mexican hospital are set forth in Part 405, Subpart A of this chapter.

H. A new Part 418 is added as set forth below:

PART 418—HOSPICE CARE

Subpart A—General Provisions and Definitions

Sec.
418.1 Statutory basis.
418.2 Scope of part.
418.3 Definitions.

Subpart B—Eligibility, Election and Duration of Benefits

Sec.
418.20 Eligibility requirements.
418.22 Certification of terminal illness.
418.24 Election of hospice care.
418.26 Elements of the election statement.
418.28 Revoking the election of hospice care.
418.30 Change of the designated hospice.
418.32 Duration of hospice coverage under Medicare.

Subpart C—Conditions of Participation

418.50 Condition of participation—General provisions.

Administration

418.52 Condition of participation—Governing body.
418.54 Condition of participation—Medical director.
418.56 Condition of participation—Professional management.
418.58 Condition of participation—Plan of care.
418.60 Condition of participation—Continuation of care.
418.62 Condition of participation—Informed consent.
418.64 Condition of participation—In-service training.
418.66 Condition of participation—Quality assurance.
418.68 Condition of participation—Interdisciplinary group.
418.70 Condition of participation—Volunteers.
418.72 Condition of participation—Licensure.
418.74 Condition of participation—Central clinical records.

Core Services

418.80 Condition of participation—Core services.
418.82 Condition of participation—Nursing services.
418.84 Condition of participation—Medical social services.
418.86 Condition of participation—Physician services.
418.88 Condition of participation—Counseling services.

Other Servies

418.90 Condition of participation—Other services.
418.92 Condition of participation—Physical therapy, occupational therapy, and speech-language pathology.
418.94 Condition of participation—Home health aide and homemaker services.
418.96 Condition of participation—Medical supplies.
418.98 Condition of participation—Short term inpatient care.

Freestanding Hospice With Inpatient Unit

418.100 Condition of participation for freestanding hospices providing inpatient care directly.

Subpart D—Covered Services

418.200 Requirements for coverage.
418.202 Covered Services.
Sec.
418.204 Special coverage requirements.

Subpart E—Reimbursement Methods

418.301 Reimbursement for hospice care.
418.302 Payment procedures for hospice care.
418.304 Payment to the hospice for physician services.
418.306 Determination of payment rates.
418.308 Limitation on the amount of hospice payments.
418.309 Determination of the hospice cap amount.
418.310 Reporting and recordkeeping requirements.
418.311 Administrative appeals.

Subpart F—Coinsurance

418.400 Individual liability for coinsurance for hospice care.
418.402 Individual liability for services that are not considered hospice care.
418.405 Reduction of Medicare reimbursement by individual coinsurance liability.

Authority: Secs. 1102, 1811–1814, 1861–1866, and 1871, Social Security Act (42 U.S.C. 1395c–1395f, 1395x–1395cc and 1395hh).

Subpart A—General Provisions and Definitions

§ 418.1 Statutory basis.

This part implements section 1861(dd) of the Social Security Act. Section 1861(dd) specifies services covered as hospice care and the conditions that a hospice program must meet in order to participate in the Medicare program. The following sections of the Act are also pertinent:

(a) Sections 1812(a) (4) and (d) of the Act specify eligibility requirements for the individual and the benefit periods.

(b) Section 1813(a)(4) of the Act specifies coinsurance amounts.

(c) Sections 1814(a)(8) and 1814(i) of the Act contain conditions and limitations on coverage of and reimbursement for hospice care.

(d) Sections 1862(a) (1), (6) and (9) of the Act establish limits on hospice coverage.

§ 418.2 Scope of part.

Subpart A of this part sets forth the statutory basis and scope and defines terms used in this part. Subpart B specifies the eligibility requirements and the benefit periods. Subpart C specifies conditions of participation for hospices. Subpart D describes the covered services and specifies the limits on services covered as hospice care. Subpart E specifies the reimbursement methods and procedures. Subpart F specifies coinsurance amounts applicable to hospice care.

§ 418.3 Definitions.

For purposes of this part—

"Attending physician" means a physician who—

(a) Is a doctor of medicine or osteopathy; and

(b) Is identified by the individual, at the time he or she elects to receive hospice care, as having the most significant role in the determination and delivery of the individual's medical care.

"Bereavement counseling" means counseling services provided to the individual's family after the individual's death.

"Cap period" means the twelve month period ending October 31 used in the application of the cap on overall hospice reimbursement specified in § 418.309.

"Carrier" means an organization that has a contract with HCFA to administer the Medicare's supplementary medical insurance program.

"Election period" means one of three periods for which individual may elect to receive Medicare coverage of hospice care. The periods consist of two 90-day periods and one 30-day period.

"Employee" means an employee (defined by section 210(j) of the Act) of the hospice or, if the hospice is a subdivision of an agency or organization, an employee of the agency or organization who is assigned and works substantially full time for the hospice unit. "Employee" also refers to a volunteer under the jurisdiction of the hospice.

"Freestanding hospice" means a hospice that is not part of any other type of participating provider.

"Hospice" means a public agency or private organization or subdivision of either of these that—

(a) Is primarily engaged in providing care to terminally ill individuals; and

(b) Meets the conditions specified in §§ 418.50–418.98 and has a valid provider agreement and if it is a freestanding hospice that provides inpatient care directly, meets the condition in § 418.100.

"Intermediary" means an organization that has a contract with the Secretary to administer the benefits covered by Medicare's hospital insurance program, including the benefits covered under this part.

"Physician" means physician as defined in § 405.232a of this chapter.

"Social worker" means a person who has at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education.

"Terminally ill" means that the individual has a medical prognosis that his or her life expectancy is 6 months or less.

Subpart B—Eligibility, Election and Duration of Benefits

§ 418.20 Eligibility requirements.

In order to be eligible to elect hospice care under Medicare, an individual must be—

(a) Entitled to Part A of Medicare; and

(b) Certified as being terminally ill in accordance with § 418.22.

§ 418.22 Certification of terminal illness.

(a) *Obtaining certification.* The hospice must obtain the certification that an individual is terminally ill in accordance with the following procedures:

(1) For the first 90-day period of hospice coverage, the hospice obtains, no later than two calendar days afer hospice care is initiated, written certification statements signed by—

(i) The medical director of the hospice or the physician member of the hospice interdisciplinary group; and

(ii) The individual's attending physician if the individual has an attending physician.

(2) For the subsequent 90-day or 30-day period, the hospice obtains, no later than two calendar days after the beginning of that period, a written certification statement prepared by the medical director of the hospice or the physician member of the hospice's interdisciplinary group.

(b) *Certification statement.* The certification must include—

(1) The statement that the individual's medical prognosis is that his or her life expectancy is six months or less; and

(2) The signature(s) of the physician(s) required to certify the terminal illness under paragraph (a) of this section.

(c) *Maintaining a record.* The hospice maintains the certification statements.

§ 418.24 Election of hospice care.

(a) *Election statement.* If an individual who meets the eligibility requirements for hospice car elects to receive that care, he or she must file an election statement with a particular hospice. The election statement must include the elements specified in § 418.26.

(b) *Sequence of election periods.* The two 90-day election periods must be used before the 30-day period.

(c) *Duration of election.* An election to receive hospice care will be considered to continue through the initial election period and through the subsequent election periods without a break in care as long as the individual—

(1) Remains in the care of a hospice; and

(2) Does not revoke the election under the provisions of §418.28.

(d) *Effective date of election.* (1) An individual may designate an effective date for the election period that begins with the first day of hospice care of any subsequent day of hospice care.

(2) An individual may not designate an effective date that is earlier than the date that the election is made.

(e) *Waiver of other benefits.* An individual must waive all rights to Medicare payments for the duration of the election of hospice care for the following services:

(1) Hospice care provided by a hospice other than the hospice designated by the individual (unless provided under arrangements made by the designated hospice).

(2) Any Medicare services that are related to the treatment of the terminal condition for which hospice care was elected or a related condition or that are equivalent to hospice care except for services—

(i) Provided by the designated hospice;

(ii) Provided by another hospice under arrangements made by the designated hospice; and

(iii) Provided by the individual's attending physician if that physician is not an employee of the designated hospice or receiving compensation from the hospice for those services.

§ 418.26 Elements of the election statement.

The election statement must include the following:

(a) Identification of the particular hospice that will provide care to the individual.

(b) Individual's acknowledgement of terminal illness.

(c) Individual's acknowledgement that he or she understands that certain Medicare services are waived by the election.

(d) The effective date of the election.

(e) The signature of the individual.

§ 418.28 Revoking the election of hospice care.

(a) An individual may revoke his or her election of hospice care at any time during an election period.

(b) To revoke the election of hospice care, the individual must file a statement with the hospice that includes the following information:

(1) A signed statement that the individual revokes his or her election for Medicare coverage of hospice care for the remainder of that election period.

(2) The date that the revocation is to be effective. (An individual may not designate an effective date earlier than the date that the revocation is made).

(c) An individual, upon revoking the election of Medicare coverage of hospice care for a particular election period—

(1) Is no longer covered under Medicare for hospice care;

(2) Resumes Medicare coverage of the benefits waived under §418.24(e)(2); and

(3) May at any time elect to receive hospice coverage for any other hospice election periods that he or she is eligible to receive.

§ 418.30 Change of the designated hospice.

(a) An individual may change, once in each election period, the designation of the particular hospice from which he or she elects to receive hospice care.

(b) The change of the designated hospice is not considered a revocation of the election for the period in which it is made.

(c) to change the designation of hospice programs, the individual must file, with the hospice from which he or she has received care and with the newly designated hospice, a statement that includes the following information:

(1) The name of the hospice from which the individual has received care and the name of the hospice from which he or she plans to receive care.

(2) The date the change is to be effective.

§ 418.32 Duration of hospice coverage under Medicare.

(a) *General rule.* Except as provided under paragaph (b) of this section, Medicare coverage of hospice care will end on September 30, 1986.

(b) *Exception.* Medicare coverage of hospice care will continue beyond September 30, 1986 for an individual who has an election in effect on that date. Medicare coverage of hospice care will continue for that individual until—

(1) The end of the election period in effect; and

(2) The end of any consecutive election period(s) that the individual would have been entitled to on September 30, 1986.

Subpart C—Conditions of Participation

§ 418.50 Condition of participation—General provisions.

(a) *Standard: Compliance.* A hospice must maintain compliance with the conditions in §§ 418.50–418.98. A freestanding hospice that provides inpatient services directly must also maintain compliance with the condition in § 418.100.

(b) *Standard: Required services.* A hospice must be primarily engaged in providing the care and services described in § 418.202, must provide bereavement counseling and must—

(1) Make all services available on a 24-hour basis to meet the needs of its patients;

(2) Provide these services in a manner consistent with accepted standards of practice; and

(3) Provide these services to the extent necessary to meet the needs of individuals for care that is reasonable and necessary for the palliation and management of terminal illness and related conditions.

Administration

§ 418.52 Condition of participation—Governing body.

A hospice must have a governing body that assumes full legal responsibility for determining, implementing and monitoring policies governing the hospice's total operation. The governing body must also ensure that all services provided are consistent with accepted standards of practice.

§ 418.54 Condition of participation—Medical director.

The medical director must be a doctor of medicine or osteopathy who assumes overall responsibility for the hospice's patient care program.

§ 418.56 Condition of participation—Professional management.

Subject to the conditions of participation pertaining to services in §§ 418.80 and 418.90, a hospice may arrange for another individual or entity to furnish services to the hospice's patients. If services are provided under arrangement, the hospice must meet the following standards:

(a) *Standard: Continuity of care.* The hospice program assures the continuity of patient/family care in home, outpatient, and inpatient settings through a defined process of—

(1) Admission to the program that includes written admission criteria and initial assessment of the patient's/family's need and decision for care;

(2) Ongoing assessment of patient/family needs;

(3) Prompt development and review of the interdisciplinary group plan of care; and

(4) Provision of adequate and appropriate patient/family information at the point of transfer between care settings.

(b) *Standard: Written agreement.* The hospice has a legally binding written agreement for the provision of arranged services. The agreement includes at least the following:

(1) Identification of the services to be provided.

(2) A stipulation that services may be provided only with the express authorization of the hospice.

(3) The manner in which the contracted services are coordinated, supervised, and evaluated by the hospice.

(4) The role(s) of the hospice and the contractor in the intake process, patient/family assessment, and the interdisciplinary group care conferences are delineated.

(c) *Standard: Professional management responsibility.* The hospice retains professional management responsibility for those services and ensures that they are furnished in a safe and effective manner by employees meeting the qualificaitons of this part, and in accordance with requirements of this part.

(d) *Standard: Financial responsibility.* The hospice retains responsibility for payment for services.

(e) *Standard: Inpatient care.* The hospice ensures that inpatient care is furnished only in a facility which meets the requirements in § 418.98 and its arrangement for inpatient care is described in a legally binding written agreement which specifies, at a minimum—

(1) What services are provided by each party to the agreement;

(2) Requirements for documenting that services are furnished in accordance with the agreement;

(3) The qualifications of the personnel providing the services;

(4) Delineation of the financial liability and responsibility of the hospice and the other party to the agreement;

(5) That this hospice furnishes to the inpatient provider a copy of the hospice plan of care and specifies the inpatient services to be furnished;

(6) That the patient care management and plan of care decisions are the ultimate responsibility of the hospice interdisciplinary group;

(7) The manner in which the services are initiated and coordinated;

(8) That the inpatient provider has established policies consistent with those of the hospice and agrees to abide by the patient care protocols established by the hospice for its patients;

(9) That the medical record includes a record of all inpatient services and events and that a copy of the medical record and discharge summary are provided to the hospice;

(10) Specification of the individuals responsible for the implementation of the provisions of the agreement; and

(11) That the hospice retains responsibility for orientation and

continuing education of the personnel who provide the care under the agreement.

§ 418.58 Conditions of participation—Plan of care.

A written plan of care must be established and maintained for each individual admitted to a hospice program, and the care provided to an individual must be in accordance with the plan.

(a) *Standard: Establishment of plan.* The plan must be established by the attending physician, the medical director and interdisciplinary group prior to providing care.

(b) *Standard: Review of plan.* The plan must be reviewed and updated, at intervals specified in the plan, by the attending physician, the medical director and interdisciplinary group. These reviews must be documented.

(c) *Standard: Content of plan.* The plan must include assessment of the individual's needs and identification of the services including the management of discomfort and symptom relief. It must state in detail the scope and frequency of services needed to meet the patient's and family's needs.

§ 418.60 Condition of participation—Continuation of care.

A hospice may not discontinue or diminish care provided to an individual because of the individual's inability to pay for that care.

§ 418.62 Condition of participation—Informed consent.

A hospice must demonstrate respect for an individual's rights by ensuring that every individual has signed an informed consent form that specifies the type of care and services that may be provided as hospice care during the course of the illness.

§ 418.64 Condition of participation—In-service training.

A hospice must provide an ongoing program for the training and continuing education of its employees.

§ 418.66 Condition of participation—Quality assurance.

A hospice must conduct an ongoing, comprehensive, integrated, self-assessment of the quality and appropriateness of care provided, including inpatient care and family care. The findings are used by the hospice to correct identified problems and to revise hospice policies if necessary.

(a) *Standard: Evaluation of care.* The governing body, through the hospice medical director, provides the support necessary for patient care monitoring activities and for problem identification and resolution activities. The medical staff and interdisciplinary group members—

(1) Implement and report on activities and mechanisms for monitoring the quality of patient care;

(2) Identify and resolve problems; and

(3) Make suggestions for improving patient care.

(b) *Standard: Evaluation of hospice program.* Representatives of the governing body, hospice interdisciplinary group, home care and inpatient services, and (where applicable) the organized staff of the inpatient service, monitor and evaluate the care they provide.

§ 418.68 Condition of participation—Interdisciplinary group.

The hospice must designate an interdisciplinary group composed of hospice employees to provide or supervise the care and services offered by the hospice.

(a) *Standard: Composition of group.* The hospice must have an interdisciplinary group that includes at least the following individuals:

(1) A doctor of medicine or osteopathy.

(2) A registered nurse.

(3) A social worker.

(4) A pastoral or other counselor.

(b) *Standard: Role of group.* The interdisciplinary group is responsible for—

(1) Participation in the establishment of the plan of care;

(2) Provision or supervision of hospice care and services;

(3) Periodic review and updating of the plan of care for each individual receiving hospice care; and

(4) Establishment of policies governing the day-to-day provision of hospice care and services.

(c) *Standard: Coordinator.* The hospice must designate a registered nurse to coordinate the overall plan of care for each patient.

§ 418.70 Condition of participation—Volunteers.

The hospice uses volunteers, in defined roles, under the supervision of designated qualified hospice staff members.

(a) *Standard: Training.* The hospice must provide appropriate orientation and training that is—

(1) Consistent with acceptable standards of hospice practice; such as the physiological/psychological aspects of terminal disease coping, family dynamics, bereavement, etc.;

(2) Appropriate to the anticipated responsibility of the volunteer; and

(3) Inclusive of, but not limit to the following:

(i) Goals and mission of the hospice program's services.

(ii) Need for patient confidentiality.

(iii) Response procedures for medical emergency and death.

(b) *Standard: Role.* Volunteers may be used in administrative and direct patient care roles. However, any direct patient care delivered by volunteers must be consistent with—(1) The interdisciplinary group plan of care; and (2) The volunteer's skills and qualifications.

(c) *Standard: Recruiting and retaining.* The hospice must document active and ongoing efforts to recruit and retain volunteers.

(d) *Standard: Evaluation.* The hospice volunteer services must be evaluated in accordance with the purposes and functions delineated by the governing body of the hospice.

(e) *Standard: Cost saving.* The hospice must document the cost savings achieved through the use of volunteers. Documentation must include—

(1) The identification of necessary positions which were occupied by volunteers;

(2) The work time spent by volunteers occupying those positions; and

(3) Estimates of the dollar costs which the hospice would have incurred if paid employees occupied the positions identified in paragraph (e) (1) for the amount of time specified in paragraph (e)(2).

(f) *Standard: Level of activity.* The hospice must document a continuing level of volunteer activity. Expansion of care and services achieved through the use of volunteers, including the type of services and the time worked, must be recorded.

(g) *Standard: Availability of clergy.* The hospice must make reasonable efforts to arrange for visits of clergy and other members of religious organizations in the community to patients who desire such visits and must advise patients of this opportunity.

§ 418.72 Condition of participation—Licensure.

The hospice and all hospice employees must be licensed in accordance with applicable State and local laws and regulations.

(a) *Standard: Licensure of program.* If State or local law privides for licensing of hospices, the hospice must be licensed.

(b) *Standard: Licensure of employees.* Employees who provide services must be licenced, certified or registered in accordance with applicable State laws.

§ 418.74 Condition of participation—Central clinical records.

In accordance with accepted prinicples of practice, the hospice must establish and maintain a clinical record for every individual receiving care and services. The record must be complete, promptly and accurately documented, readily accessible and systematically organized to facilitate retrieval.

(a) *Standard: Content.* Each clinical record is a comprehensive compilation of information. Entries are made for all services provided. Entries are made and signed by the staff providing the services. The record includes all services whether furnished directly or under arrangements made by the hospice. Each individual's record contains—

(1) The initial and subsequent assessments;

(2) The plan of care;

(3) identification data;

(4) Consent and authorization and election forms;

(5) Pertinent medical history; and

(6) Complete documentation of all services and events (including evaluations, treatments, progress notes, etc.).

(b) *Standard: Protection of information.* The hospice must safeguard the clinical record against loss, destruction and unauthorized use.

Core Services

§ 418.80 Condition of participation—Core services.

A hospice must ensure that substantially all the core services described in §§ 418.82–418.88 are routinely provided directly by hospice employees. A hospice may use contracted staff if necessary to supplement hospice employees in order to meet the needs of patients during periods of peak patient loads or under extraordinary circumstances. If contracting is used, the hospice must maintain professional, financial, and administrative responsibility for the services and must assure that the qualifications of staff and services provided meet the requirements specified in §§418.82–418.88.

§ 418.82 Conditions of participation—Nursing services.

The hospice must provide nursing care and services by or under the supervision of a registered nurse.

(a) Nursing services must be directed and staffed to assure that the nursing needs of patients are met.

(b) Patient care responsibilities of nursing personnel must be specified.

(c) Services must be provided in accordance with recognized standards of practice.

§ 418.84 Condition of participation—Medical social services.

Medical social services must be provided by a qualified social worker, under the direction of a physician.

§ 418.86 Conditions of participation—Physician services.

Physician employees of the hospice, including the physician member(s) of the interdisciplinary group, must care for the general medical needs of the patients for palliation and management of terminal illness and related conditions.

§ 418.88 Condition of participation—Counseling services.

Counseling services must be available to both the individual and the family. Counseling includes bereavement counseling, dietary, spiritual and any other counseling services for the individual and family while the individual is enrolled in the hospice.

(a) *Standard: Bereavement counseling.* There must be an organized program for the provision of bereavement services under the supervision of a qualified professional. The plan of care for these services should reflect family needs, as well as a clear delineation of services to be provided and the frequency of service delivery (up to one year following the death of the patient). Special coverage requirements for bereavement counseling are described in § 418.204(c).

(b) *Standard: Dietary counseling.* Dietary counseling, when required, must be provided by a qualified individual.

(c) *Standard: Spiritual counseling.* Spiritual counseling must include notice to patients as to the availability of clergy as provided in § 418.70(g).

Other Services

§ 418.90 Condition of participation—Other services.

A hospice must ensure that the services described in §§ 418.92–418.98 are provided directly by hospice employees or under arrangements made by the hospice as specified in § 418.56

§ 418.92 Condition of participation—Physical therapy, occupational therapy, and speech-language pathology.

Physical therapy services, occupational therapy services, and speech-language pathology services must be available, and when provided, offered in a manner consistent with accepted standards of practice.

§ 418.94 Condition of participation—Home health aide and homemaker services.

Home health aide and homemaker services must be available and adequate in number to meet the needs of the patients. A home health aide is a person who meets the training, attitude and skill requirements specified in § 405.1227 of this chapter.

(a) *Standard: Supervision.* Aide services must be provided under the general supervision of a registered nurse who makes a supervisory visit to the home site at least every 2 weeks to assess relationships and determine whether goals are being met.

(b) *Standard: Duties.* Written instructions for patient care are prepared by a registered nurse. Duties include, but may not be limited to, the duties specified in § 405.1227(a) of this chapter.

§ 418.96 Condition of participation—Medical supplies.

Medical supplies and appliances, including drugs and biologicals, must be provided as needed for the palliation and management of the terminal illness and related conditions. All drugs and biologicals must be administered in accordance with acceptable standards of practice.

(a) *Standard: Orders for medications.* (1) A physician must call all medications for the patient.

(2) If the medication order is given orally—

(i) The physician must give it only to a licensed nurse, pharmacist, or another physician; and

(ii) The individual receiving the order must record and sign it immediately and the prescribing physician must sign it in a manner consistent with good medical practice.

(b) *Standard: Administration of pharmaceuticals.* Pharmaceuticals are administered only by the following individuals:

(1) A licensed nurse or physician.

(2) An employee who has completed a State-approved training program in medication administration.

(3) The patient if his or her attending physician has approved.

(c) *Standard: Drug records and disposition.* Records of the receipt and disposition of all controlled drugs furnished by the hospice are maintained to enable an accurate reconciliation.

(d) *Standard: Drug storage and security.* Drugs are stored in locked compartments under proper temperature controls and only authorized staff have access to the keys.

(e) *Standard: Drug disposal.* Controlled drugs no longer needed by

the patient, whether maintained in the home or in the hospice, are disposed of in compliance with State requirements. In the absence of State requirements, two hospice employees destroy the drugs and prepare a record of the disposal.

§ 418.98 Condition of participation—Short term inpatient care.

Impatient care must be available for pain control, symptom management and respite purposes.

(a) *Standard: Inpatient care.* Inpatient care must be provided in one of the following participating Medicare or Medicaid facilities that is most appropriate to the needs of the individual:

(1) A hospice that meets the condition of participation for providing inpatient care directly as specified in § 418.100.

(2) A hospital, an SNF, or an ICF that also meets the standards specified in § 418.100(a) and (f) regarding staffing and patient areas.

(b) *Standard: Inpatient care limitation.* Except as provided in paragraph (c) of this section, the total number of inpatient days used by Medicare beneficiaries who elected hospice coverage in any 12-month period preceding a certification survey in a particular hospice may not exceed 20 percent of the total number of hospice days for this group of beneficiaries.

(c) *Standard: Exemption from limitation.* Until October 1, 1986, any hospice that began operation before January 1, 1975 is not subject to the limitation specified in paragraph (b).

Freestanding Hospice with Inpatient Unit

§ 418.100 Condition of participation for freestanding hospices providing inpatient care directly.

A freestanding hospice that provides inpatient care directly must comply with the following standards.

(a) *Standard: Staffing.* (1) The hospice must have staff on duty 24 hours a day sufficient in number and qualifications to carry out the policies—and responsibilities of the hospice.

(2) Each shift must include a registered nurse who provides direct patient care; except that in the case of respite care, a registered nurse is necessary only during the day shift.

(3) During each shift, every patient must be under the direct care of a registered nurse or a licensed practical nurse.

(b) *Standard: Emergencies.* The hospice must—

(1) Have a written plan for staff and patients to follow in case of an emergency such as a fire or an explosion and rehearse the plan regularly; and

(2) Have written procedures for the staff to follow in case of an emergency involving a patient. These emergency procedures must include directions for—

(i) Caring for the patient;

(ii) Notifying the attending physician and other individuals responsible for the patient, and

(iii) Arranging for transportation, hospitalization, or other appropriate services.

(c) *Standard: Health and safety laws.* The hospice must meet all Federal, State, and local laws, regulations, and codes pertaining to health and safety, such as provisions regulating—

(1) Construction, maintenance, and equipment for the hospice

(2) Sanitation;

(3) Communicable and reportable diseases; and

(4) Post mortem procedures.

(d) *Standard: Fire protection.* Except as provided in paragraph (e) of this section, the hospice must meet the health care occupancy provisions of the 1981 edition of the Life Safety Code of the National Fire Protection Association which is incorporated by reference [1]

(e) *Standard: Fire protection waivers.* (1) In consideration of a recommendation by the State survey agency, HCFA may waive specific provisions of the Life Safety Code required by paragraph (d) of this section, for as long as it considers appropriate, if—

(i) The waiver would not adversely affect the health and safety of the patients; and

(ii) Rigid application of specific provisions of the Code would result in unreasonable hardship for the hospice.

(2) Any facility of two or more stories that is not of fire resistive construction and is participating on the basis of a waiver of construction type or height, may not house blind, nonambulatory, or physically handicapped patients above the street-level floor unless the facility—

(i) Is one of the following construction types (as defined in the Life Safety Code)—

(A) Type II (1, 1, 1)—protected noncombustible;

(B) Fully sprinklered Type II (0, 0, 0)—noncombustible

(C) Fully sprinklered Type III (2, 1, 1)—protected ordinary;

(D) Fully sprinklered Type V (1, 1, 1)—protected wood frame; or

(ii) Achieves a passing score on the Fire Safety Evaluation System (FSES) or FSES/Board and Care.

[1] See footnote to § 405.1022(b) of this chapter.

(f) *Standard: Patient areas.* (1) the hospice must design and equip areas for the comfort and privacy of each patient and family members.

(2) In areas that are designated for hospice care, the hospice must have—

(i) Physical space for private patient/family visiting;

(ii) Accommodations for family members to remain with the patient throughout the night;

(iii) Accommodations for family privacy after a patient's death;

(iv) Decor which is homelike in design and function; and

(v) Oxygen must be available for patients, as needed.

(3) Patients must be permitted to receive visitors, including small children.

(g) *Standard: Patients' rooms.* (1) Each patient's room must—

(i) Be equipped with or conveniently located near toilet and bathing facilities;

(ii) Be at or above grade level;

(iii) Contain a suitable bed for each patient and other appropriate furniture;

(iv) Have closet space that provides security and privacy for clothing and personal belongings;

(v) Contain no more than four beds;

(vi) Measure at least 100 square feet for a single patient room or 80 square feet for each patient for a multipatient room; and

(vii) Be equipped with a device for calling the staff member on duty.

(2) For an existing building, HCFA may waive the space and occupancy requirements of paragraphs (g)(1) (v) and (vi) of this section for as long as it is considered appropriate if it finds that—

(i) The requirements would result in unreasonable hardship on the hospice if strictly enforced; and

(ii) The waiver serves the particular needs of the patients and does not adversely affect their health and safety.

(h) Standard: Bathroom facilities. The hospice must—

(1) Provide an adequate supply of hot water at all times for patient use; and

(2) Have plumbing fixtures with control valves that automatically regulate the temperature of the hot water used by patients.

(i) Standard: Linen supplies. The hospice must have available at all times enough linen for the proper care and comfort of the patients and have clean linen on each bed.

(j) Standard: Isolation areas. The hospice must make provision for isolating patients with infectious diseases.

(k) Standard: Dining, recreation and social rooms. The hospice must provide one or more areas, not used for corridor

traffic, for dining, recreation, and social activities.

(l) Standard: Meal service. The hospice must—

(1) Serve at least three meals or their equivalent each day at regular times, with not more than 14 hours between a substantial evening meal and breakfast;

(2) Procure, store, prepare, distribute, and serve all food under sanitary conditions; and

(m) Standard: Menu planning and supervision.

(1) The hospice must have a staff member trained or experienced in food management or nutrition who is responsible for—

(i) Planning menus that meet the nutritional needs of each patient, following the orders of the patient's physician and, to the extent medically possible, the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences (Recommended Dietary Allowances (9th ed., 1981) is available from the Printing and Publications Office, National Academy of Sciences, Washington, D.C. 20418); and

(ii) Supervising the meal preparation and service to insure that the menu plan is followed.

(2) If the hospice has patients who require medically prescribed special diets, the hospice must—

(i) Have the menus for those patients planned by a professionally qualified dietitian; and

(ii) Supervise the preparation and serving of meals to insure that the patient accepts the special diet.

(n) Standard: Licensed pharmacist. The hospice must—

(1) Employ a licensed pharmacist; or

(2) Have a formal agreement with a licensed pharmacist to advise the hospice on ordering, storage, administration, disposal, and recordkeeping of drugs and biologicals.

(o) Standard: Orders for medications.

(1) A physician must order all medications for the patient.

(2) If the medication order is verbal—

(i) The physician must give it only to a licensed nurse, pharmacist, or another physician; and

(ii) The individual receiving the order must record and sign it immediately and have the prescribing physician sign it in a manner consistent with good medical practice.

(p) *Standard: Administering medications.* Medications are administered only by one of the following individuals:

(1) A licensed nurse or physician.

(2) An employee who has completed a State-approved training program in medication administration.

(3) The patient if his or her attending physician has approved.

(q) *Standard: Supervision.* The hospice must have a registered nurse to supervise the hospice health services full time, 7 days a week, on each shift.

Subpart D—Covered Services

§ 418.200 Requirements for coverage.

To be covered, hospice services must be reasonable and necessary for the palliation or management of the terminal illness as well as related conditions. The individual must elect hospice care in accordance with § 418.24 and a plan of care must be established as set forth in § 418.58 before services are provided. To be covered, services must be consistent with the plan of care. A certification that the individual is terminally ill must be completed as set forth in § 418.22.

§ 418.202 Covered services.

All services must be performed by appropriately qualified personnel, but it is the nature of the service, rather than the qualification of the person who provides it, that determines the coverage category of the service. The following services are covered hospice services:

(a) Nursing care provided by or under the supervision of a registered nurse.

(b) Medical social services provided by a social worker under the direction of a physician.

(c) Physicians' services performed by a physician as defined in § 405.232a of this chapter except that the services of the hospice medical director or the physician member of the interdisciplinary group must be performed by a doctor of medicine or osteopathy.

(d) Counseling services provided to the terminally ill individual and the family members or other persons caring for the individual at home. Counseling, including dietary counseling, may be provided both for the purpose of training the individual's family or other care-giver to provide care, and for the purpose of helping the individual and those caring for him or her to adjust to the individual's approaching death.

(e) Short-term inpatient care provided in a participating hospice inpatient unit, or a participating hospital, SNF, or ICF that additionally meets the standards in § 418.100 (a) and (f) regarding staffing and patient areas. Services provided in an inpatient setting must conform to the written plan of care. Inpatient care may be required for procedures necessary for pain control or acute or chronic symptom management.

Inpatient care may also be furnished as a means of providing respite for the individual's family or other persons caring for the individual at home. Payment for inpatient care will be made at the rate appropriate to the level of care as specified in § 418.302.

(f) Medical appliances and supplies, including drugs and biologicals. Only drugs as defined in section 1861(t) of the Act and which are used primarily for the relief of pain and symptom control related to the individual's terminal illness are covered. Appliances may include covered durable medical equipment as described in § 405.231(g) of this chapter as well as other self-help and personal comfort items related to the palliation or management of the patient's terminal illness. Equipment is provided by the hospice for use in the patient's home while he or she is under hospice care. Medical supplies include those that are part of the written plan of care.

(g) Home health aide services furnished by qualified aides as designated in § 418.94 and homemaker services. Home health aides may provide personal care services as described in § 405.127(d) of this chapter. Aides may also perform household services to maintain a safe and sanitary environment in areas of the home used by the patient, such as changing the bed or light cleaning and laundering essential to the comfort and cleanliness of the patient. Aide services must be provided under the general supervision of a registered nurse. Homemaker services may include assistance in personal care, maintenance of a safe and healthy environment and services to enable the individual to carry out the treatment plan.

(h) Physical therapy, occupational therapy and speech-language pathology services in addition to the services described in § 405.127(c) of this chapter provided for purposes of symptom control or to enable the patient to maintain activities of daily living and basic functional skills.

§ 418.204 Special coverage requirements.

(a) *Periods of crisis.* Nursing care may be covered on a continuous basis for as much as 24 hours a day during periods of crisis as necessary to maintain an individual at home. Either homemaker or home health aide services or both may be covered on a 24-hour continuous basis during periods of crisis but care during these periods must be predominantly nursing care. A period of crisis is a period in which the individual requires continuous care to achieve

palliation or management of acute medical symptoms.

(b) *Respite care.* (1) Respite care is short-term inpatient care provided to the individual only when necessary to relieve the family members or other persons caring for the individual.

(2) Except as provided in paragraph (b)(3), respite care may be provided only on an occasional basis and may not be reimbursed for more than five consecutive days at a time.

(3) Until October 1, 1986, any hospice that began operation before January 1, 1975 is not subject to the limitation on the frequency and number of respite care days.

(c) *Bereavement counseling.* Bereavement counseling is a required hospice service but it is not reimbursable.

Subpart E—Reimbursement Methods

§ 418.301 Reimbursement for hospice care.

(a) Medicare payment for covered hospice care is made in accordance with the method set forth in § 418.302.

(b) Medicare reimbursement to a hospice in a cap period is limited to an amount determined in accordance with § 418.309.

§ 418.302 Payment procedures for hospice care.

(a) HCFA establishes payment amounts to reimburse specific categories of covered hospice care.

(b) Payment amounts are determined within each of the following categories:

(1) *Routine home care day.* A routine home car day is a day on which an individual who has elected to receive hospice care is at home and is not receiving continuous care as defined in paragraph (b)(2) of this section.

(2) *Continuous home care day.* A continuous home care day is a day on which an individual who has elected to receive hospice care is not in an inpatient facility and receives hospice care consisting predominantly of nursing care on a continuous basis at home. Home health aide or homemaker services or both may also be provided on a continuous basis. Continuous home care is only furnished during brief periods of crisis as described in § 418.204(a) and only as necessary to maintain the terminally ill patient at home.

(3) *Inpatient respite care day.* An inpatient respite care day is a day other than an inpatient care day on which the individual who has elected hospice care receives care in an approved facility on a short-term basis for respite.

(4) *General inpatient care day.* A general inpatient care day is a day on which an individual who has elected hospice care receives general inpatient care in an inpatient facility for pain control or acute or chronic symptom management which cannot be managed in other settings.

(c) The payment amounts for the categories of hospice care are fixed payment rates that are calculated by HCFA in accordance with the procedures described in § 418.306. Payment rates are determined for the following categories:

(1) Routine home care.

(2) Continuous home care.

(3) Inpatient respite care.

(4) General inpatient care.

(d) The intermediary reimburses the hospice at the appropriate payment amount for each day for which an eligible Medicare beneficiary is under the hospice's care.

(e) The intermediary makes payment according to the following procedures:

(1) Payment is made to the hospice for each day during which the beneficiary is eligible and under the care of the hospice, regardless of the amount of services furnished on any given day.

(2) Payment is made for only one of the categories of hospice care described in § 418.302(b) for any particular day.

(3) On any day on which the beneficiary is not an inpatient, the hospice is paid the routine home care rate, unless the patient receives continuous care as defined in paragraph (b)(2) of this section for a period of at least 8 hours. In that case, a portion of the continuous care day rate is paid in accordance with paragraph (4) of this section.

(4) The continuous home care day rate is divided into 3 portions. The hospice payment on a continuous care day varies depending on the length of continuous services provided, as follows—

(i) For 8 up to 16 hours of care, the hospice is paid one-half the rate;

(ii) For 16 up to 20 hours of care, the hospice is paid three-fourths of the rate; and

(iii) For 20 through 24 hours of care, the hospice is paid eleven-twelfths of the continuous care day rate.

(5) Subject to the limitations described in paragraph (f) of this section, on any day on which the beneficiary is an inpatient in an approved facility for inpatient care, the appropriate inpatient rate (general or respite) is paid depending on the category of care furnished. The inpatient rate (general or respite) is paid for the date of admission and all subsequent inpatient days, except the day on which the patient is discharged. For the day of discharge, the appropriate home care rate is paid unless the patient dies as an inpatient. In the case where the beneficiary is discharged deceased, the inpatient rate (general or respite) is paid for the discharge day. Payment for inpatient respite care is subject to the requirement that it may not be provided consecutively for more than 5 days at a time. Payment for the sixth and any subsequent day of respite care is made at the routine home care rate.

(f) Payment for inpatient care is limited as follows: (1) That Total payment to the hospice for inpatient care (general or respite) is subject to a limitation that total inpatient care days for Medicare patients not exceed 20 percent of the total days for which these patients had elected hospice care.

(2) At the end of a cap period, the intermediary calculates a limitation on payment for inpatient care to ensure that Medicare payment is not made for days of inpatient care in excess of 20 percent of the total number of days of hospice care furnished to Medicare patients.

(3) If the number of days of inpatient care furnished to Medicare patients is equal to or less than 20 percent of the total days of hospice care to Medicare patients, no adjustment is necessary. Overall payments to a hospice are subject to the cap amount specified in $418.309.

(4) If the number of days of inpatient care furnished to Medicare patients exceeds 20 percent of the total days of hospice care to Medicare patients, the total payment for inpatient care that was made is multiplied by the proportion of the maximum number of allowable inpatient care days to the actual number of inpatient care days furnished by the hospice to Medicare patients. This amount is compared to actual payments for inpatient care, and any excess reimbursement must be refunded by the hospice. Overall payments to the hospice are subject to the cap amount specified in § 418.309.

§ 418.304 Payment to the hospice for physician services.

(a) The following service perfomed by hospice physicians are inluded in the rates described in § 418.302:

(1) General supervisory services of the medical director.

(2) Interdisciplinary group services of the interdisciplinary group physician member.

(b) The carrier pays the hospice an amount equivalent to 100 percent of the physician's reasonable charge for those physician services furnished by hospice employees or under arrangements with the hospice. Reimbursement for these

physician services is included in the amount subject to the hospice payment limit described in § 418.309. Services furnished voluntarily by physicians are not reimbursable.

(c) Services of the patient's attending physician, if he or she is not an employee of the hospice or providing services under arrangements with the hospice, are not considered hospice services and are not included in the amount subject to the hospice payment limit described in § 418.309. These services are paid by the carrier under the procedures in Subparts D or E, Part 405 of this chapter.

§ 418.306 Determination of the payment rates.

(a) HCFA calculates payment rates for each of the categories of hospice care described in § 418.302(c).

(b) Each rate is equal to a prospectively determined amount which HCFA estimates equals the costs incurred by hospice generally in efficiently providing that type of hospice care to Medicare beneficiaries.

(c) The rates are adjusted by the intermediary to reflect local differences in wages.

(d) HCFA will publish as a notice in the **Federal Register** any proposal to change payment rates or the methodology for determining those rates.

§ 418.308 Limitation on the amount of hospice payments.

(a) Except as specified in paragraph (b) of this section, the total Medicare payment to a hospice for care furnished during a cap period is limited by the hospice cap amount that is determined in accordance with § 418.309.

(b) Until October 1, 1986, payment to a hospice that began operation before January 1, 1975 is not limited by the amount of the hospice cap described in § 418.309.

(c) The intermediary notifies the hospice of the determination of program reimbursement at the end of the cap year in accordance with procedures similar to those described in 42 CFR 405.1803.

(d) Payments made to a hospice during cap period that exceed the cap amount are overpayments and must be refunded.

§ 418.309 Determination of the hospice cap amount.

The hospice cap amount is calculated using the following procedures:

(a) HCFA calculates the national average Medicare per capita expenditure for the last six months of life for beneficiaries whose primary cause of death was cancer. This figure is determined using data from a base year established by HCFA.

(b) Using an index that relates the level of Medicare expenditures in a region to the national level, HCFA calculates a regional average Medicare per capita expenditure for each region based on the national average. (NOTE: final rule will define region and describe the method of indexing.)

(c) The regional per capita expenditure calculated under paragraph (b) of this section is adjusted for deflation or inflation using the percentage change in the consumer price index (CPI) for medical care expenditures for urban consumers that is published by the Bureau of Labor Statistics. This adjustment is made using the change in the CPI from the fourth month of the base year to the fifth month of the cap years. The cap year runs from November 1 of each year until October 31 of the following year.

(d) Each hospice's cap amount is calculated by the intermediary by multiplying 40 percent of the adjusted regional per capita expenditure amount (as determined in paragraph (c) of this section) by the number of Medicare beneficiaries who elected to receive hospice care from that hospice during the cap period. For purposes of this calculation, the number of Medicare beneficiaries includes—

(1) Those Medicare beneficiaries who have not previously been included in the calculation of any hospice cap and who have filed an election to receive hospice care, in accordance with $418.24, from the hospice during the period beginning on October 10 (22 days before the beginning of the cap period) and ending on October 9 (22 days before the end of the cap period).

(2) In the case in which a beneficiary has elected to receive care from more than one hospice, each hospice includes in its number of Medicare beneficiaries only that fraction which represents the portion of a patient's total stay in all hospices that was spend in that hospice. (The hospice can obtain this information by contacting the intermediary.)

§ 418.310 Reporting and recordkeeping requirements.

Hospices must provide reports and keep records as the Secretary determines necessary to administer the program.

§ 418.311 Administrative appeals.

A hospice that believes its payments have not been properly determined in accordance with these regulations may request a review from the intermediary or the Provider Reimbursement Review Board (PRRB). In such a case, the procedure in 42 CFR Part 405, Subpart R, will be followed to the extent that it is applicable. The PRRB, subject to review by the Secretary under § 405.1874 of this chapter, shall have the authority to determine the issues raised.

Subpart F—Coinsurance

§ 418.400 Individual liability for coinsurance for hospice care.

An individual who has filed an election for hospice care in accordance with § 418.24 is liable for the following coinsurance payments. Hospices may charge individuals the applicable coinsurance amounts.

(a) *Drugs and biologicals.* An individual is liable for a coinsurance payment for each palliative drug and biological prescription furnished by the hospice while the individual is not an inpatient. The amount of coinsurance for each prescription approximates 5 percent of the cost of the drug or biological to the hospice determined in accordance with the drug copayment schedule established by the hospice, except that the amount of coinsurance for each prescription may not exceed $5. The cost of the drug or biological may not exceed what a prudent buyer would pay in similar circumstances. The drug copayment schedule must be reviewed for reasonableness and approved by the intermediary before it is used.

(b) *Respite care.* The amount of coinsurance for each respite care day is equal to 5 percent of the payment made by HCFA for a respite care day.

(2) The amount of the individual's coinsurance liability for respite care during a hospice coinsurance period may not exceed the inpatient hospital deductible applicable for the year in which the hospice coinsurance period began.

(3) The individual hospice coinsurance period—

(i) Begins on the first day an election filed in accordance with § 418.24 is in effect for the beneficiary; and

(ii) Ends with the close of the first period of 14 consecutive days on each of which an election is not in effect for the beneficiary.

§418.402 Individual liability for services that are not considered hospice care.

Medicare payment to the hospice discharges an individual's liability for payment for all services, other than the hospice coinsurance amounts described in § 418.400, that are considered covered hospice care (as described in § 418.202). The individual is liable for the Medicare deductibles and coinsurance payments and for the difference between the

reasonable and actual charge on unassigned claims on other covered services that are not considered hospice care. Examples of services not considered hospice care include: services furnished before or after a hospice election period; services of the individual's attending physician, if the attending physician is not an employee of or working under an arrangement with the hospice; or Medicare services received for the treatment of an illness or injury not related to the individual's terminal condition.

§ 418.405 Reduction of Medicare reimbursement by individual coinsurance liability.

The Medicare payment rates established by HCFA in accordance with §418.306 are not reduced when the individual is liable for coinsurance payments. Instead, when determining the payment rates, HCFA offsets the estimated cost of services by an estimate of average coinsurance amounts hospices collect.

PART 420—PROGRAM INTEGRITY

The authority citation for Part 420 reads as follows:

Authority: Secs. 1102, 1128, 1862(d), 1862(e), 1866(b)(2)(D), (E), and (F), 1871, 1902(a)(39), and 1903(i)(2) of the Social Security Act (42 U.S.C. 1302, 1320a–7, 1395y(d), 1395y(e), 1395cc(b)(2)(D), (E), and (F), 1395hh, 1396a(a)(39), and 1396b(i)(2)).

I. Part 420 is amended as follows:

1. In Subpart A, § 420.2 is amended by revising the definition of "Provider" to read as follows:

Subpart A—General Provisions

* * * * *

§ 420.2 Definitions.

* * * * *

"*Provider*" means a hospital, a skilled nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency, or a hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency, or a public health agency that has a similar agreement, but only to furnish outpatient physical therapy or speech pathology services.

* * * * *

2. In Subpart D, § 420.301, the introductory language is reprinted and the definition of "Provider" is revised to read as follows:

Subpart D—Access to Books, Documents, and Records of Subcontractors

* * * * *

§ 420.301 Definitions.

For purposes of this subpart—

* * * * *

"*Provider*" means a hospital, skilled nursing facility, home health agency, or comprehensive outpatient rehabilitation facility, a hospice, or a related organization (as defined in § 405.427 of this chapter) of any of these providers.

* * * * *

PART 421—INTERMEDIARIES AND CARRIERS

J. Part 421 is amended as follows:

1. The Table of Contents is amended by revising the title of § 421.117 to read as follows:

* * * * *

Sec.

421.117 Designation of intermediaries for freestanding home health agencies and hospices.

* * * * *

Authority: Secs. 1102, 1815, 1816, 1842, 1861(u), 1871, 1984 and 1875 of the Social Security Act (42 U.S.C. 1302, 1395g, 1395h, 1395u, 1395x(u), 1395hh, 1395kk, and 1395ll), and 42 U.S.C. 1395–1.

2. Section 421.3 is amended by revising the definitions of "Intermediary" and "Provider" to read as follows:

§ 421.3 Definitions.

* * * * *

"*Intermediary*" means an organization that has entered into an agreement with the Administrator to perform designated functions in the administration of the Medicare program.

For purposes of designating intermediaries for freestanding home health agencies and hospices under § 421.117 as well as for applying the performance criteria in § 421.120 and the statistical standards in § 421.122 and any adverse action resulting from such application, the term intermediary also means a Blue Cross Plan which has entered into a subcontract approved by the Administrator with the Blue Cross Association to perform intermediary functions.

"*Provider*" means a hospital, skilled nursing facility (SNF), home health agency (HHA), hospice, comprehensive outpatient rehabilitation facility, or a provider of outpatient physical therapy or speech pathology services under the Medicare program.

* * * * *

3. Section 421.103 is revised to read as follows:

§ 421.103 Option available to providers.

Except for hospices (which are covered under § 421.117), a provider may elect to receive payment for covered services furnished to Medicare beneficiaries:

(a) Directly from the Administrator, or

(b) Through an intermediary, when both the Administrator and the intermediary consent.

4. Section 421.104 is amended by revising paragraph (a)(1) to read as follows:

§ 421.104 Nominations for intermediary.

(a) *Nomination by groups or associations of providers.* (1) An association of providers, except for hospices, may nominate an organization or agency to serve as intermediary for its members.

* * * * *

5. Section 421.106 is amended by revising the introductory material in paragraph (a) to read as follows:

§ 421.106 Change to another intermediary or to direct payment.

(a) Any provider, except for a hospice, may request a change of intermediary, or that it be paid directly by the Administrator, by

* * * * *

6. Section 421.117 is amended by revising the title and paragraph (a), and by adding a new paragraph (c) to read as follows:

§ 421.117 Designation of intermediaries for freestanding home health agencies and for hospices.

(a) This section is based on section 1818(e)(4) of the Social Security Act, which requires the Secretary to designate regional intermediaries for freestanding home health agencies (HHAs) and on section 1816(e)(5) of the Social Security Act, which requires the Secretary to designate intermediaries for hospices.

* * * * *

(c) Except for certain hospice physician services, which generally are reimbursed by carriers, hospices receive payment for covered services furnished to Medicare beneficiaries in accordance with the following:

(1) Freestanding hospices receive payment through an intermediary designated by HCFA.

(2) Except as described in paragraph (c)(3), hospices that are subdivisions of other Medicare providers receive payment through the same intermediary that serves their parent provider.

(3) A hospice whose parent provider is served by HCFA receives payment through an intermediary designated by HCFA.

7. Section 421.128 is amended by revising paragraph (f) to read as follows:

§ 421.128 Intermediary's opportunity for a hearing and right to judicial review.

* * * * *

(f) Exception. An intermediary adversely affected by the designation of an intermediary under § 421.117 of this subpart is not entitled to a hearing or judicial review concerning adverse effects caused by the designation of an intermediary.

PART 489—PROVIDER AGREEMENTS UNDER MEDICARE

The authority citation for Part 489 reads as follows:

Authority: Sec. 1102, 1814(a) and 1866, Social Security Act (42 U.S.C. 1302, 1395f(a) and 1395cc).

K. Part 489 is amended as follows:

1. Section 489.2 is amended by adding a new paragraph (b)(6) to read as follows:

§ 489.2 Scope of part.

* * * * *

(b) The following providers are subject to the provisions of this part:

* * * * *

(6) Hospices.

2. Section 489.55 is amended by revising paragraph (b) to read as follows:

§ 489.55 Exceptions to effective date of termination.

* * * * *

(b) In the case of home health services furnished under a plan of treatment or hospice care furnished under a plan of care established before the effective date, payment may be made for services furnished through the end of the calendar year in which termination is effective.

(Catalog of Federal Domestic Assistance Program No. 13.773, Medicare Hospital Insurance)

Dated: August 3, 1983.

Carolyne K. Davis,

Administrator, Health Care Financing Administration.

Approved: August 16, 1983.

Margaret M. Heckler,

Secretary.

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