under this part in any fiscal year by such emergency feeding organizations.

§ 251.9 Miscellaneous provisions.

(a) *Records.* (1) State agencies and emergency feeding organizations shall maintain records to document the receipt, disposal and inventory of commodities received under this part in accordance with requirements of § 250.6(r) of this chapter. (2) In addition to maintaining financial records in accordance with 7 CFR Part 3015, State agencies which receive funds under this part shall maintain records to document that the amount of funds paid to emergency feeding organizations for the actual storage and distribution costs incurred by any emergency feeding organization does not exceed 5 percent of the value of commodities distributed by such organizations in accordance with § 251.8(d)(3) of this part. State agencies shall ensure that emergency feeding organizations maintain records as required by this paragraph.

(b) *Commodities not income.* In accordance with section 206 of Pub. L. 98–8, as amended, and notwithstanding any provision of law, commodities distributed under this part shall not be considered income or resources for any purposes under any Federal, State, or local law.

(c) *Non-Discrimination.* There shall be no discrimination in the distribution of foods donated under this part because of race, color, national origin, sex, age, or handicap.

(d) *Prohibition on sale or other disposal in commercial channels.* In accordance with section 205(b) of Pub. L. 98–8, as amended, except as otherwise provided in paragraph 251.4(d) of this part, none of the commodities distributed under this part shall be sold or otherwise disposed of in commercial channels in any form.

(e) *Relationship to the Food Stamp Program.* In accordance with section 205(a) of Pub. L. 98–8, as amended, section 4(b) of the Food Stamp Act of 1977 does not apply with respect to the distribution of commodities to households under this part.

(Catalog of Federal Domestic Assistance No. 10.550)

(Sec. 210(a), Pub. L. 98–8, as amended)

Dated: December 12, 1983.

Robert E. Leard,

Administrator.

[FR Doc. 83-33423 Filed 12-15-83; 8:45 am]

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Part VI

Department of Justice

Enforcement of Nondiscrimination on the Basis of Handicap in Department of Justice Programs; Proposed Rule

DEPARTMENT OF JUSTICE

28 CFR Part 39

[Order No. 1041-83]

Enforcement of Nondiscrimination on the Basis of Handicap in Department of Justice Programs

AGENCY: Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed regulation provides for the enforcement of section 504 of the Rehabilitation Act of 1973, as amended, which prohibits discrimination on the basis of handicap, as it applies to programs or activities conducted by the Department of Justice.

DATE: To be assured of consideration, comments must be in writing and must be received on or before April 16, 1984. Comments should refer to specific sections in the regulation.

ADDRESSES: Comments should be sent to: Stewart B. Oneglia, Chief, Coordination and Review Section, Civil Rights Division, U.S. Department of Justice, Rulemaking Docket 004, P.O. Box 1019, Washington, D.C. 20013.

Comments received will be available for public inspection in Room 854 of the HOLC Building, 320 First Street, N.W., Washington, D.C. from 9:00 A.M. to 5:00 P.M., Monday through Friday except legal holidays. Copies of this notice are available on tape for those with impaired vision. They may be obtained at the above address.

FOR FURTHER INFORMATION CONTACT: John L. Wodatch, Deputy Chief, Coordination and Review Section, Civil Rights Division, U.S. Department of Justice, Washington, D.C. 20530; (202) 724-2227 (Voice) or 724-7678 (TDD); or Irene Bowen, Supervisory Attorney, Handicap Unit, Coordination and Review Section, Civil Rights Division, U.S. Department of Justice, Washington, D.C. 20530; (202) 724-2245 (Voice) or 724-7678 (TDD). These are not toll free numbers.

SUPPLEMENTARY INFORMATION:

Background

The purpose of this proposed rule is to provide for the enforcement of section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794), as it applies to programs and activities conducted by the Department of Justice. As amended by the Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978 (Sec. 119, Pub. L. 95-602, 92 Stat. 2982), section 504 of the Rehabilitation Act of 1973 states that:

> No otherwise qualified handicapped individual in the United States, * * * shall, solely by reason of his handicap, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance *or under any program or activity conducted by any Executive agency or by the United States Postal Service. The head of each such agency shall promulgate such regulations as may be necessary to carry out the amendments to this section made by the Rehabilitation, Comprehensive Services, and Developmental Disabilities Act of 1978. Copies of any proposed regulation shall be submitted to appropriate authorizing committees of the Congress, and such regulation may take effect on earlier than the thirtieth day after the date on which such regulation is so submitted to such committees.*
>
> (29 U.S.C. 794) (amendment italicized).

The substantive nondiscrimination obligations of the agency, as set forth in this proposed rule, are identical, for the most part, to those established by Federal regulations for programs or activities receiving Federal financial assistance. *See* 28 CFR Part 41 (section 504 coordination regulation for federally assisted programs). This general parallelism is in accord with the intent expressed by supporters of the 1978 amendment in floor debate, including its sponsor, Rep. James M. Jeffords, that the Federal Government should have the same section 504 obligations as recipients of Federal financial assistance. 124 Congressional Record 13,901 (1978) (remarks of Rep. Jeffords); 124 Congressional Record E2668, E2670 (daily ed. May 17, 1978) *id.*; 124 Congressional Record 13,897 (remarks of Rep. Brademas); *id.* at 38,552 (remarks of Rep. Sarasin).

This regulation is an adaptation of a prototype prepared by the Department under Executive Order 12250 (45 FR 72995, 3 CFR, 1980 Comp., p. 298) and distributed to Executive agencies on April 15, 1983.

This regulation has been reviewed by the Equal Employment Opportunity Commission under Executive Order 12067 (43 FR 28967, 3 CFR, 1978 Comp., p. 206).

It is not a major rule within the meaning of Executive Order 12291 (46 FR 13193, 3 CFR, 1981 Comp., p. 127) and therefore a regulatory impact analysis has not been perpared.

This regulation does not have an impact on small entities. It is not, therefore, subject to the Regulatory Flexibility Act (5 U.S.C. 601-612).

Section-By-Section Analysis

Section 39.101 Purpose.

Section 39.101 states the purpose of the proposed rule, which is to effectuate section 119 of the Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978, which amended section 504 of the Rehabilitation Act of 1973 to prohibit discrimination on the basis of handicap in programs or activities conducted by Executive agencies or the United States Postal Service.

Section 39.102 Application.

The proposed regulation applies to all programs or activities conducted by the agency.

Section 39.103 Definitions.

"Agency." For purposes of this regulation "agency" means the Department of Justice.

"Assistant Attorney General." "Assistant Attorney General" refers to the Assistant Attorney General, Civil Rights Division, United States Department of Justice.

"Auxiliary aids." The term "auxiliary aids" means services or devices that enable persons with impaired sensory, manual, or speaking skills to have an equal opportunity to participate in and enjoy the benefits of the agency's programs or activities. The definition provides examples of commonly used auxiliary aids. Although auxiliary aids are required explicitly only by § 39.160(a)(1), they may also be necessary to meet other requirements of the regulation.

"Complaint Adjudication Officer." "Complaint Adjudication Officer" refers to the Complaint Adjudication Officer designated by the Assistant Attorney General.

"Complete complaint." The definition of "complete complaint" enables the agency to determine the beginning of its obligation to investigate a complaint (*see* § 39.170(f) and (g)).

"Facility." The definition of "facility" is similar to that in section 504 coordination regulation for federally assisted programs, 28 CFR 41.3(f), except that the term "rolling stock or other conveyances" has been added and the phrase "or interest in such property" has been deleted to clarify its coverage. The term "facility" is used in § 39.150 and § 39.170(e).

"Handicapped person." The definition of "handicapped person" is a shortened version of the definition appearing in the section 504 coordination regulation for federally assisted programs (28 CFR 41.31). In the interest of brevity, examples of handicapping conditions appearing under the term "physical or mental impairment" are deleted.

"Official" or "Responsible Official" refers to the Director of Equal Employment Opportunity for the Department of Justice, with responsibilities for administration of the Equal Employment Opportunity Program within the Department. The Assistant Atforney General for Administration has been designated as the Director of Equal Employment Opportunity for the Department of Justice. 28 CFR 42.2(a).

"Qualified handicapped person." The definition of "qualified handicapped person" is a revised version of the definition appearing in the section 504 coordination regulation for federally assisted programs (28 CFR 41.32).

Subparagraph (1) deviates from existing regulations for federally assisted programs because of intervening court decisions. It defines "qualified handicapped person" with regard to any program under which a person is required to perform services or to achieve a level of accomplishment. In such programs a qualified handicapped person is one who can achieve the purpose of the program without modifications in the program that would result in a fundamental alteration in its nature. This definition reflects the decision of the Supreme Court in *Southeastern Community College v. Davis*, 442 U.S. 397 (1979). In that case, the Court ruled that a hearing-impaired applicant to a nursing school was not a "qualified handicapped person" because her hearing impairment would prevent her from participating in the clinical training portion of the program. The Court found that, if the program were modified so as to enable the respondent to participate (by exempting her from the clinical training requirements), "she would not receive even a rough equivalent of the training a nursing program normally gives." *Id.* at 410. It also found that "the purpose of [the] program was to train persons who could serve the nursing profession in all customary ways," *id.* at 413, and that the respondent would be unable, because of her hearing impairment, to perform some functions expected of a registered nurse. It therefore concluded that the school was not required by section 504 to make such modifications that would result in "a fundamental alteration in the nature of the program." *Id.* at 410.

We have incorporated the Court's language in the definition of "qualified handicapped person" in order to make clear that such a person must be able to participate in the program offered by the agency. The agency is required to make modifications in order to enable a handicapped applicant to participate, but is not required to offer a program of a fundamentally different nature. The test is whether, with appropriate modifications, the applicant can achieve the purpose of the program offered; not whether the applicant could benefit or obtain results from some other program that the agency does not offer. Although the revised definition allows exclusion of some handicapped people from some programs, it requires that a handicapped person who is capable of achieving the purpose of the program must be accommodated, provided that the modifications do not fundamentally alter the nature of the program.

For programs or activities that do not fall under the first subparagraph, subparagrahh (2) adopts the existing definition of "qualified handicapped person" with respect to services (28 CFR 41.32(b)) in the coordination regulation for programs receiving Federal financial assistance. Under his definition, a qualified handicapped person is a handicapped person who meets the essential eligibility requirements for participation in the program or activity.

"Respondent." "Respondent" refers to the organizational unit in which a complainant alleges that discrimination occurred.

"Section 504." This definition makes clear that, as used in this regulation, "section 504" applies only to programs or activities conducted by the agency and not to programs or activities to which it provides Federal financial assistance.

Section 39.110 Self-evaluation.

The agency shall conduct a self-evaluation of its compliance with section 504 within one year of the effective date of this regulation. The process shall include consultation with interested persons, including consultation with handicapped persons or organizations representing handicapped persons. The self-evaluation requirement is present in the existing section 504 coordination regulation for programs or activities receiving Federal financial assistance (28 CFR 41.5(b)(2)). Experience has demonstrated the self-evaluation process to be a valuable means of establishing a working relationship with handicapped persons that promotes both effective and efficient implementation of section 504.

Section 39.130 General prohibitions against discrimination.

Section 39.130 is an adaptation of the corresponding section of the section 504 coordination regulation for programs or activities receiving Federal financial assistance (28 CFR 41.51).

Paragraph (a) restates the nondiscrimination mandate of section 504. The remaining paragraphs in § 39.130 establish the general principles for analyzing whether any particular action of the agency violates this mandate. These principles serve as the analytical foundation for the remaining sections of the regulation. Whenever the agency has violated a provision in any of the subsequent sections, it has also violated one of the general prohibitions, found in § 39.130. When there is no applicable subsequent provision, the general prohibitions stated in this section apply.

Paragraph (b) prohibits overt denials of equal treatment of handicapped persons. Thus, the agency may not, solely because the person is disabled, refuse to provide a handicapped person with an equal opportunity to participate in or benefit from its program. Such blatantly exclusionary practices often result from the use of irrebuttable presumptions that absolutely exclude certain classes of disabled persons (*e.g.*, epileptics, hearing-impaired persons, persons with heart ailments) from participation in programs or activities without regard to an individual's actual ability to participate. Use of an irrebuttable presumption is permissible only when in all cases a physical condition by its very nature would prevent an individual from meeting the essential eligibility requirements for participation in the activity in question.

Section 504, however, prohibits more than just the most obvious denials of equal treatment. It is not enough to admit persons in wheelchairs to a program if the facilities in which the program is conducted are inaccessible. Subparagraph (b) (1)(iii), therefore, requires that the opportunity to participate or benefit afforded to a handicapped person be as effective as that afforded to others. The later sections on program accessibility (§§ 39.150–39.151) and communications (§ 39.160) are specific applications of this principle.

Despite the mandate of paragraph (d) that the agency administer its programs and activities in the most integrated setting appropriate to the needs of qualified handicapped persons, subparagraph (b)(1)(iv), in conjunction with paragraph (d), permits the agency to develop separate or different aids, benefits, or services when necessary to provide handicapped persons with an equal opportunity to participate in or benefit from the agency's programs or activities. Subparagraph (b)(1)(iv) requires that different or separate aids, benefits, or services be provided only

when necessary to ensure that the aids, benefits, or services are as effective as those provided to others. Even when separate or different aids, benefits, or services would be more effective, subparagraph (b)(2) provides that a qualified handicapped person still has the right to choose to participate in the program that is not designed to accommodate handicapped persons.

Subparagraph (b)(1)(v) prohibits the agency from denying a qualified handicapped person the opportunity to participate as a member of a planning or advisory board.

Subparagraph (b)(1)(vi) prohibits the agency from limiting a qualified handicapped person in the enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving any aid, benefit, or service.

Subparagraph (b)(3) prohibits the agency from utilizing criteria or methods of administration that deny handicapped persons access to the agency's programs or activities. The phrase "criteria or methods of administration" refers to official written agency policies and the actual practices of the agency. This subparagraph prohibits both grossly exclusionary policies or practices and nonessential policies and practices that are neutral on their face, but deny handicapped persons an effective opportunity to participate.

Subparagraph (b)(4) specifically applies the prohibition enunciated in § 39.130(b)(3) to the process of selecting sites for construction of new facilities or existing facilities to be used by the agency. Subparagraph (b)(4) does not apply to construction of additional buildings at an existing site.

Subparagraph (b)(5) prohibits the agency, in the selection of procurement contractors, from using criteria that subject qualified handicapped persons to discrimination on the basis of handicap.

Subparagraph (b)(6) prohibits the agency from discriminating against qualified handicapped persons on the basis of handicap in the granting of licenses or certification. A person is a "qualified handicapped person," with respect to licensing or certification, if he or she can meet the essential eligibility requirements for receiving the license or certification (*see* § 39.103).

In addition, the agency may not establish requirements for the programs or activities of licensees or certified entities that subject qualified handicapped persons to discrimination on the basis of handicap. For example, the agency must comply with this requirement when establishing safety standards for the operations of licensees. In that case the agency must ensure that standards that it promulgates do not discriminate against the employment of qualified handicapped persons in an impermissible manner.

Subparagraph (b)(6) does not extend section 504 directly to the programs or activities of licensees or certified entities themselves. The programs of activities of Federal licensees or certified entities are not themselves federally conducted programs or activities nor are they programs or activities receiving Federal financial assistance merely by virtue of the Federal license or certificate. However, as noted above, section 504 may affect the content of the rules established by the agency for the operation of the program or activity of the licensee or certified entity, and thereby indirectly affect limited aspects of their operations.

Paragraph (c) provides that programs conducted pursuant to Federal statute or Executive order that are designed to benefit only handicapped persons or a given class of handicapped persons may be limited to those handicapped persons.

Section 39.140 Employment.

Section 39.140 prohibits discrimination on the basis of handicap in employment by Executive agencies. This regulation is in accord with a recent decision of the Fifth Circuit that holds that, despite the resulting overlap of coverage with section 501 of the Rehabilitation Act of 1973 (29 U.S.C. 791), Congress intended section 504 to cover the employment practices of Executive agencies. The court also held that in order to give effect to both section 504 and section 501, the administrative procedures of section 501 must be followed in processing section 504 complaints. *Prewitt* v. *United States Postal Service*, 662 F.2d 292 (5th Cir. 1981).

Consistent with that decision, this section provides that the standards, requirements, and procedures of section 501 of the Rehabilitation Act, as established in regulations of the Equal Employment Opportunity Commission (EEOC) at 29 CFR Part 1613, shall be those applicable to employment in federally conducted programs or activities. In addition to this section, § 39.170(b) of this regulation specifies that the agency will use the existing EEOC procedures to resolve allegations of employment discrimination. Responsibility for coordinating enforcement of Federal laws prohibiting discrimination in employment is assigned to the EEOC by Executive Order 12067 (3 CFR, 1978 Comp., p. 206). Under this authority, the EEOC establishes government-wide standards on nondiscrimination in employment on the basis of handicap.

Section 39.150 Program accessibility: Existing facilities.

This regulation adopts the program accessibility concept found in the existing section 504 coordination regulation for programs or activities receiving Federal financial assistance (28 CFR 41.56–41.58), with certain modifications. Thus, § 39.150 requires that the agency's program or activity, when viewed in its entirety, be readily accessible to and usable by handicapped persons. The regulation also makes clear that the agency is not required to make each of its existing facilities accessible (§ 39.150(a)(1)). However, § 39.150, unlike 28 CFR 41.56–41.57, places explicit limits on the agency's obligation to ensure program accessibility (§ 39.150(a)(2)).

Subparagraph (a)(2) generally codifies recent case law that defines the scope of the agency's obligation to ensure program accessibility. This subparagraph provides that in meeting the program accessibility requirement the agency is not required to take any action that would result in a fundamental alteration in the nature of its program or activity or in undue financial and administrative burdens. A similar limitation is provided in § 39.160(e). This provision is based on the Supreme Court's holding in *Southeastern Community College* v. *Davis*, 442 U.S. 397 (1979), that section 504 does not require program modifications that result in a fundamental alteration in the nature of a program, and on the Court's statement that section 504 does not require modifications that would result in "undue financial and administrative burdens." 442 U.S. at 412. Since *Davis*, circuit courts have applied this limitation on a showing that only one of the two "undue burdens" would be created as a result of the modification sought to be imposed under section 504. *See, e.g., Dopico* v. *Goldschmidt*, 687 F.2d 644 (2d Cir. 1982); *American Public Transit Association* v. *Lewis (APTA)*, 655 F.2d 1272 (D.C. Cir. 1981). Thus, in *APTA* the United States Court of Appeals for the District of Columbia Circuit applied the *Davis* language and invalidated the section 504 regulations of the Department of Transportation. The court in *APTA* noted "that at some point a transit system's refusal to take modest, affirmative steps to accommodate handicapped persons

might well violate section 504. But DOT's rules do not mandate only modest expenditures. The regulations require extensive modifications of existing systems and impose extremely heavy financial burdens on local transit authorities." 655 F.2d at 1278.

The inclusion of subparagraph (a)(2) is an effort to conform the agency's regulation implementing section 504 to the Supreme Court's interpretation of the statute in *Davis* as well as to the decisions of lower courts following the *Davis* opinion. This subparagraph acknowledges, in light of recent case law, that in some situations, certain accommodations for a handicapped person may so alter an agency's program or activity, or entail such extensive costs and administrative burdens that the refusal to undertake the accommodations is not discriminatory. The failure to include such a provision could lead to judicial invalidation of the regulation or reversal of a particular enforcement action taken pursuant to the regulation.

This subparagraph, however, does not establish an absolute defense; it does not relieve the agency of all obligations to handicapped persons. Although the agency is not required to take actions that would result in a fundamental alteration in the nature of a program or activity or in undue financial and administrative burdens, it nevertheless must take any other steps necessary to ensure that handicapped persons receive the benefits and services of the federally conducted program or activity.

Paragraph (b) sets forth a number of means by which program accessibility may be achieved, including redesign of equipment, reassignment of services to accessible buildings, and provision of aides. In choosing among methods, the agency shall give priority consideration to those that will be consistent with provision of services in the most integrated setting appropriate to the needs of handicapped persons. Structural changes in existing facilities are required only when there is no other feasible way to make the agency's program accessible. The agency may comply with the program accessibility requirement by delivering services at alternate accessible sites or making home visits as appropriate.

Paragraphs (c) and (d) establish time periods for complying with the program accessibility requirement. As currently required for federally assisted programs by 28 CFR 41.57(b), the agency must make any necessary structural changes in facilities as soon as practicable, but in no event later than three years after the effective date of this regulation. Where structural modifications are required, a transition plan shall be developed within six months of the effective date of this regulation. Aside from structural changes, all other necessary steps to achieve compliance shall be taken within sixty days.

Section 39.151 Program accessibility: New construction and alterations.

Overlapping coverage exists with respect to new construction under section 504, section 502 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 792), and the Architectural Barriers Act of 1968, as amended (42 U.S.C. 4151–4157). Section 39.151 provides that those buildings that are constructed or altered by, on behalf of, or for the use of the agency shall be designed, constructed, or altered to be readily accessible to and usable by handicapped persons in accordance with 41 CFR 101–19.600 to 101.607. This standard was promulgated pursuant to the Architectural Barriers Act of 1968, as amended (42 U.S.C. 4151–4157). We believe that it is appropriate to adopt the existing Architectural Barriers Act standard for section 504 compliance because new and altered buildings subject to this regulation are also subject to the Architectural Barriers Act and because adoption of the standard will avoid duplicative and possible inconsistent standards.

Existing buildings leased by the agency after the effective date of this regulation are not required to meet the new construction standard. They are subject, however, to the requirements of § 39.150.

Section 39.160 Communications.

Section 39.160 requires the agency to take appropriate steps to ensure effective communication with personnel of other Federal entities, applicants, participants, and members of the public. These steps shall include procedures for determining when auxiliary aids are necessary under § 39.160(a)(1) to afford a handicapped person an equal opportunity to participate in, and enjoy the benefits of, the agency's program or activity. They shall also include an opportunity for handicapped persons to request the auxiliary aids of their choice. This expressed choice shall be given primary consideration by the agency (§ 39.160(a)(1)(i)). The agency shall honor the choice unless it can demonstrate that another effective means of communications exists or that use of the means chosen would not be required under § 39.160(e). That paragraph limits the obligation of the agency to ensure effective communication in accordance with *Davis* and the circuit court opinions interpreting it (*see supra* preamble § 39.150(a)(2)). Unless not required by § 39.160(e), the agency shall provide auxiliary aids at no cost to the handicapped person.

In some circumstances, a notepad and written materials may be sufficient to permit effective communication with a hearing-impaired person. In many circumstances, however, they may not be, participant where the hearing-impaired applicant or participant is not skilled in spoken or written language. Then, a sign language interpreter may be appropriate. For vision-impaired persons, effective communication might be achieved by several means, including readers and audio recordings. In general, the agency intends to make clear to the public (1) the communications services it offers to afford handicapped persons an equal opportunity to participate in or benefit from its program or activities, (2) the opportunity to request a particular mode of communication, and (3) the agency's preferences regarding auxiliary aids if it can demonstrate that several different modes are effective.

The agency shall ensure effective communication with vision-impaired and hearing-impaired persons involved in hearings conducted by the agency. Auxiliary aids must be afforded where necessary to ensure effective communication at the proceedings. If sign language interpreters are necessary, the agency may require that it be given reasonable notice prior to the proceeding of the need for an interpreter. Moreover, the agency need not provide individually prescribed devices, readers for personal use or study, or other devices of a personal nature (§ 39.160(a)(1)(ii). For example, the agency need not provide eyeglasses or hearings aids to applicants or participants in its programs. Similarly, the regulation does not require the agency to provide wheelchairs to persons with mobility impairments.

While each agency is required to provide auxiliary aids for handicapped persons where necessary, the agency may coordinate with other agencies or offices occupying the same building to implement this requirement. For example, one agency can obtain a TDD and share it with the other agencies or offices provided that such coordination is adequate to ensure effective communication with hearing-impaired persons. Otherwise, it would be necessary to provide additional TDD's. At any rate, an agreement with another agency does not relieve the agency from its responsibility to furnish aids where necessary.

Paragraph (b) requires the agency to provide information to handicapped persons concerning accessible services, activities, and facilities. For example, the Department of Justice has taken steps to make known the availability of its Sensory Assistance Center, a service center and training facility for sight-impaired attorneys employed by the Federal Government. It contains state-of-the-art electronic devices, such as reading machines and talking computer terminals, for use by sight-impaired attorneys in reading, writing, and legal research.

Paragraph (c) requires the agency to provide signage at inaccessible facilities that directs users to locations with information about accessible facilities.

Paragraph (d) requires the agency to take appropriate steps to provide handicapped persons with information regarding their section 504 rights under the agency's programs and activities. Methods of providing this information include, for example, the publication of information in handbooks, manuals, and pamplets that are distributed to the public to describe the agency's programs and activities; the display of informative posters in service centers and other public places; or the broadcast of information by television or radio.

Section 39.170 Compliance Procedures.

Paragraph (a) specifies that paragraphs (c) through (l) of this section establish the procedures for processing complaints other than employment complaints. Paragraph (b) provides that the agency will process employment complaints according to procedures established in existing regulations of the EEOC (29 CFR Part 1613) pursuant to section 501 of the Rehabilitation Act of 1973 (29 U.S.C. 791).

Paragraph (c) vests in the Responsible Official the responsibility for the overall management of the 504 compliance program.

"Responsible Official" or "Official," as defined in § 39.103, refers to the Director of Equal Employment Opportunity, who is designated as the official responsible for coordinating implementation of compliance procedures set forth in § 39.170. The definition of "Official" includes other Department Officials to whom authority has been delegated by the Official. The Assistant Attorney General for Administration has been designated as the Director of Equal Employment Opportunity for the Department.

It should be emphasized that, although one person has responsibility both for administering the Equal Employment Opportunity Program for the Department and for coordinating implementation of the compliance procedures under this part, the procedures for carrying out these responsibilities are different. The Official would follow the procedures for enforcing equal employment opportunity, as set forth in 29 CFR 1613.701–1613.710, only for complaints alleging employment discrimination (See § 39.170(b)). Other complaints would be processed under the procedures in § 39.170. Authority for processing complaints of employment discrimination has been delegated to Equal Employment Opportunity Officers in some Department components, and it is expected that authority for enforcing this part will be similarly delegated.

Subparagraphs (d) (1) and (3) provide that any person who believes that he, she, or a specific class of persons has been discriminated against may file a complaint within 180 days from the date of the alleged discrimination. The Official may extend the time limit when the complainant shows good cause. Good cause could be found if, for example, (1) the complainant mistakenly filed with the wrong agency and was not informed of the mistake within the 180 days; or (2) the complainant could not reasonably be expected to know of the act or event said to be discriminatory.

The Federal Bureau of Prisons has established an Administrative Remedy Procedure for handling grievances of inmates of Federal penal institutions (28 CFR Part 542). This procedure allows an inmate to file a formal written complaint with the Warden of the Institution or with the Regional Director. Decisions of the Warden must generally be made within 15 days and may be appealed to the Regional Director.

The Regional Director has 30 days to respond to a complaint and 20 days to respond to an appeal. The response of the Regional Director may be appealed to the General Counsel. While we do not believe that these remedies are an adequate substitute for the right to an independent investigation by a civil rights office and appeal to the Complaint Adjudication Officer, we believe it might be appropriate to require inmates to exhaust these procedural remedies before filing a complaint with the Official. The time period for filing with the Official would be extended by the time spent exhausting these remedies. This requirement applies only to inmates and does not extend to visitors and employees. We request comments on the question of how inmate complaints should be handled.

Subparagraph (d)(2) requires that the name and identity of a complainant be held in confidence unless he or she waives that right in writing and except to the extent necessary for compliance purposes.

Complaints may be mailed or delivered to the Attorney General, the Responsible Official, or other agency officials. Complaints received by any agency official other than the Responsible Official must be forwarded immediately to the Responsible Official (subparagraph (d)(4)).

Paragraph (e) requires the agency to send to the Architectural and Transportation Barriers Compliance Board a copy of any complaint alleging that a building or facility subject to the Architectural Barriers Act or section 502 was designed, constructed, or altered in a manner that does not provide ready access to and use by handicapped persons.

The Official is required to accept all complete complaints over which the agency has jurisdiction (§ 39.170(f)(1)). If the Official determines that the agency does not have jurisdiction over a complaint, the Official shall promptly notify the complainant and make reasonable efforts to refer the complaint to the appropriate entity of the Federal government (§ 39.170(f)(3)).

If a complaint is not complete when it is filed, the Official must notify the complainant within 30 days that additional information is needed. The complainant must furnish the necessary information within 30 days of receipt of the notice, or the complaint will be dismissed without prejudice. Filing an incomplete complaint within 180 days from the date of the alleged discrimination satisfies the requirement of subparagraph (d)(3), but the time frames governing the Official's other obligations to process the complaint (*see, e.g.*, § 39.170(g)(1), § 39.170(h)) do not begin to operate until the Official receives a complete complaint.

Within 180 days of receipt of the complete complaint, the Official is to investigate the complaint, attempt an informal resolution, and, if informal resolution is not achieved, issue a letter of preliminary findings (§ 39.170(h)). Within the time limit, the Official should make every effort to achieve informal resolution whenever possible.

Paragraph (h) requires that the Official's letter be sent to the complainant and respondent, and that it contain findings of fact and conclusions of law, the relief granted if discrimination is found, and notice of the right to appeal. If neither party files an appeal from the letter of preliminary findings within 30 days after receipt of the letter, the letter will constitute the final decision of the agency (§ 39.170(i)).

The regulation provides that a party may appeal the Official's letter of preliminary findings to the Complaint Adjudication Officer (CAO). In addition, the proposal expands on the Department's prototype regulation by providing an opportunity for a hearing before an adminsitrative law judge (ALJ). The ALJ would make a recommended decision to the CAO, who would make the final agency decision. The purpose of the hearing is to provide a forum in which the complainant or respondent can have an opportunity to be heard, confront witnesses, and present evidence so that an administrative law judge can issue a recommended decision that is well-reasoned and justified on the basis of the evidence presented.

It would be expected that an opportunity for a hearing before an ALJ would assure more impartiality or the appearance of more impartiality than a decision made by one agency official concerning other officials of the same agency. It would also be expected that agency decisions based on a hearing record would more likely survive later judicial review.

On the other hand, a more streamlined procedure without the opportunity for a hearing would ensure more rapid agency decisions on complaints. As a result, complainants could obtain agency relief more quickly in those instances where they prevailed. We seek comment on the merits of allowing the opportunity for a hearing.

We also seek comment on the appropriateness of providing for an appeal by either the complainant or respondent. Would it be more appropriate to allow the complainant, but not the respondent, to appeal?

Under the proposal another person or organization would be allowed to participate as a third party or amicus curiae if the ALJ determines that the petitioner has a legitimate interest in the proceedings, that participation will not unduly delay the outcome, and that petitioner's participation may contribute materially to the dispostiion of the proceedings.

Under paragraph (l), the Complaint Adjudication Officer renders a final agency decision after appeal without a hearing or after a hearing. The Complaint Adjudication Officer directs appropriate remedial action if discriminatioin is found. The Complaint Adjudication Officer's decision will involve rerviewing the entire file, including the investigation report, preliminary findings, and, if a hearing was held, the hearing record and recommended decision of the administrative law judge. If it is the decision of the CAO to reject or modify the recommended decision of the judge, the reasons for the rejection or modification will be put in writing and made part of the decision (§ 39.170(l)(1)). The decision shall be made within 60 days of receipt of the complaint file or the hearing record.

List of Subjects in 28 CFR Part 39

Blind, Civil rights, Deaf, Disabled, Discrimination against handicapped, Equal educational opportunity, Equal employment opportunity, Federal buildings and facilities, Handicapped, Nondiscrimination, Physically handicapped.

By the authority vested in me as Attorney General by 28 U.S.C. 509, 510, 5 U.S.C. 301, and section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), and for the reasons set forth in the preamble, Chapter I of title 28 of the Code of Federal Regulations is proposed to be amended by adding a new Part 39 as follows:

PART 39—ENFORCEMENT OF NONDISCRIMINATION ON THE BASIS OF HANDICAP IN PROGRAMS OR ACTIVITIES CONDUCTED BY THE DEPARTMENT OF JUSTICE

Sec.

39.101 Purpose.
39.102 Application.
39.103 Definitions.
39.104–39.109 [Reserved]
39.110 Self-evaluation.
39.111–39.129 [Reserved]
39.130 General prohibitions against discrimination.
39.131–39.139 [Reserved]
39.140 Employment.
39.141–39.149 [Reserved]
39.150 Program accessibility: Existing facilities.
39.151 Program accessibility: New construction and alterations.
39.152–39.159 [Reserved]
39.160 Communications.
39.161–39.169 [Reserved]
39.170 Compliance procedures.
39.171–39.999 [Reserved]

Authority: 29 U.S.C. 794.

§ 39.101 Purpose.

The purpose of this part it to effectuate section 119 of the Rehabilitation, Comprehensive Services and Developmental Disabilities Amendments of 1978, which amends section 504 of the Rehabilitation Act of 1973 to prohibit discrimination on the basis of handicap in programs or activities conducted by Executive agencies or the United States Postal Service.

§ 39.102 Application.

This part applies to all programs or activities conducted by the agency.

§ 39.103 Definitions.

For purposes of this part, the term—

"Agency" means the Department of Justice.

"Assistant Attorney General" means the Assistant Attorney General, Civil Rights Division, United States Department of Justice.

"Auxiliary aids" means services or devices that enable persons with impaired sensory, manual, or speaking skills to have an equal opportunity to participate in, and enjoy the benefits of, programs or activities conducted by the agency. For example, auxiliary aids useful for persons with impaired vision include readers, Brailled materials, audio recordings, telecommunications devices, and other similar services and devices. Auxiliary aids useful for persons with impaired hearing include telephone handset amplifiers, telephones, compatible with hearing aids, telecommunications devices for deaf persons (TDD's), interpreters, notetakers, written materials, and other similar services and devices.

"Complaint Adjudication Officer" means the Complaint Adjudication Officer appointed by the Assistant Attorney General for Civil Rights.

"Complete complaint" means a written statement that contains the complainant's name and address and describes the agency's action in sufficient detail to inform the agency of the nature and date of the alleged violation of section 504. It shall be signed by the complainant or by someone authorized to do so on his or her behalf. Complaints filed on behalf of classes shall describe or identify (by name, if possible) the alleged victims of discrimination.

"Facility" means all or any portion of buildings, structures, equipment, roads, walks, parking lots, rolling stock or other conveyances, or other real or personal property.

"Handicapped person" means any person who has a physical or mental impairment that substantially limits one or more major life activities, has a record or such an impairment, or is regarded as having such an impairment.

As used in this definition, the phrase:

(1) "Physical or mental impairment" includes—

(i) Any physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting one or more of the following body systems: Neurological; musculoskeletal; special sense organs; respiratory, including

speech organs; cardiovascular; reproductive; digestive; genitourinary; hemic and lymphatic; skin; and endocrine; or

(ii) Any mental or psychological disorder, such as mental retardation, organic brain syndrome, emotional or mental illness, and specific learning disabilities.

(2) "Major life activities" includes functions such as caring for one's self, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, and working.

(3) "Has a record of such an impairment" means has a history of, or has been misclassified as having, a mental or physical impairment that substantially limits one or more major life activities.

(4) "Is regarded as having an impairment" means—

(i) Has a physical or mental impairment that does not substantially limit major life activities but is treated by the agency as constituting such a limitation;

(ii) Has a physical or mental impairment that substantially limits major life activities only as a result of the attitudes of others toward such impairment; or

(iii) Has none of the impairments defined in paragraph (1) of this definition but is treated by the agency as having such an impairment.

"Official" or "Responsible Official" means the Director of Equal Employment Opportunity for the Department of Justice or his or her designee.

"Qualified handicapped person" means—

(1) With respect to any agency program or activity under which a person is required to perform services or to achieve a level of accomplishment, a handicapped person who meets the essential eligibility requirements and who can achieve the purpose of the program or activity without modifications in the program or activity that would result in a fundamental alteration in its nature; and

(2) With respect to any other program or activity, a handicapped person who meets the essential eligibility requirements for participation in, or receipt of benefits from, that program or activity.

"Respondent" means the organizational unit in which a complainant alleges that discrimination occurred.

"Section 504" means section 504 of the Rehabilitation Act of 1973 (Pub. L. 93–112, 87 Stat. 394 (29 U.S.C. 794)), as amended by the Rehabilitation Act Amendments of 1974 (Pub. L. 93–516, 88 Stat. 1617), and the Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978 (Pub. L. 95–602, 92 Stat. 2955). As used in this part, section 504 applies only to programs or activities conducted by Executive agencies and not to federally assisted programs.

§§ 39.104–39.109 [Reserved]

§ 39.110 Self-evaluation.

Within one year of the effective date of this part, the agency shall conduct, with the assistance of interested persons, including handicapped persons or organizations representing handicapped persons, a self-evaluation of its compliance with section 504.

§§ 39.111–39.129 [Reserved]

§ 39.130 General prohibitions against discrimination.

(a) No qualified handicapped person shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any program or activity conducted by the agency.

(b)(1) The agency, in providing any aid, benefit, or service, may not, directly or through contractual, licensing, or other arrangements, on the basis of handicap—

(i) Deny a qualified handicapped person the opportunity to participate in or benefit from the aid, benefit, or service;

(ii) Afford a qualified handicapped person an opportunity to participate in or benefit from the aid, benefit, or service that is not equal to that afforded others;

(iii) Provide a qualified handicapped person with an aid, benefit, or service that is not as effective in affording equal opportunity to obtain the same result, to gain the same benefit, or to reach the same level of achievement as that provided to others;

(iv) Provide different or separate aid, benefits, or services to handicapped persons or to any class of handicapped persons than is provided to others unless such action is necessary to provide qualified handicapped persons with aids, benefits, or services that are as effective as those provided to others;

(v) Deny a qualified handicapped person that opportunity to participate as a member of planning or advisory boards; or

(vi) Otherwise limit a qualified handicapped person in the enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving the aid, benefit, or service.

(2) The agency may not deny a qualified handicapped person the opportunity to participate in programs or activities that are not separate or different, despite the existence of permissibly separate or different programs or activities.

(3) The agency may not, directly or through contractual or other arrangements, utilize criteria or methods of administration the purpose or effect of which would—

(i) Subject qualified handicapped persons to discrimination on the basis of handicap; or

(ii) Defeat or substantially impair accomplishment of the objectives of a program or activity with respect to handicapped persons.

(4) The agency may not, in determining the site or location of a facility, make selections the purpose or effect of which would—

(i) Exclude handicapped persons from, deny them the benefits of, or otherwise subject them to discrimination under any program or activity conducted by the agency; or

(ii) Defeat or substantially impair the accomplishment of the objectives of a program or activity with respect to handicapped persons.

(5) The agency, in the selection of procurement contractors, may not use criteria that subject qualified handicapped persons to discrimination on the basis of handicap.

(6) The agency may not administer a licensing or certification program in a manner that subjects qualified handicapped persons to discrimination on the basis of handicap, nor may the agency establish requirements for the programs or activities of licensees or certified entities that subject qualified handicapped persons to discrimination on the basis of handicap. However, the programs or activities of entities that are licensed or certified by the agency are not, themselves, covered by this part.

(c) The exclusion of nonhandicapped persons from the benefits of a program limited by Federal statute or Executive order to handicapped persons or the exclusion of a specific class of handicapped persons from a program limited by Federal statute or Executive order to a different class of handicapped persons is not prohibited by this part.

(d) The agency shall administer programs and activities in the most integrated setting appropriate to the needs of qualified handicapped persons.

§§ 39.131–.139 [Reserved]

§ 39.140 Employment.

No qualified handicapped person shall, on the basis of handicap, be subjected to discrimination in employment under any program or activity conducted by the agency. The definitions, requirements, and procedures of section 501 of the Rehabilitation Act of 1973 (29 U.S.C. 791), as established in 29 CFR Part 1613, shall apply to employment in federally conducted programs or activities.

§§ 39.141–39.149 [Reserved]

§ 39.150 Program accessibility: Existing facilities.

(a) *General.* The agency shall operate each program or activity so that the program or activity, when viewed in its entirety, is readily accessible to and usable by handicapped persons. This paragraph does not—

(1) Necessarily require the agency to make each of its existing facilities accessible to and usable by handicapped persons; or

(2) Require the agency to take any action that it can demonstrate would result in a fundamental alteration in the nature of a program or activity or in undue financial and administrative burdens. If an action would result in such an alteration or such burdens, the agency shall take any other action that would not result in such an alteration or such burdens but would nevertheless ensure that handicapped persons receive the benefits and services of the program or activity.

(b) *Methods.* The agency may comply with the requirements of this section through such means as redesign of equipment, reassignment of services to accessible buildings, assignment of aides to beneficiaries, home visits, delivery of services at alternate accessible sites, alteration of existing facilities and construction of new facilities, use of accessible rolling stock, or any other methods that result in making its programs or activities readily accessible to and usable by handicapped persons. The agency is not required to make structural changes in existing facilities where other methods are effective in achieving compliance with this section. The agency, in making alterations to existing buildings, shall meet accessibility requirements to the extent compelled by the Architectural Barriers Act of 1968, as amended (42 U.S.C. 4151–4157), and any regulations implementing it. In choosing among available methods for meeting the requirements of this section, the agency shall give priority to those methods that offer programs and activities to qualified handicapped persons in the most integrated setting appropriate.

(c) *Time period for compliance.* The agency shall comply with the obligations established under this section within sixty days of the effective date of this part except that where structural changes in facilities are undertaken, such changes shall be made within three years of the effective date of this part, but in any event as expeditiously as possible.

(d) *Transition plan.* In the event that structural changes to facilities will be undertaken to achieve program accessibility, the agency shall develop, within six months of the effective date of this part, a transition plan setting forth the steps necessary to complete such changes. The plan shall be developed with the assistance of interested persons, including handicapped persons or organizations representing handicapped persons. A copy of the transition plan shall be made available for public inspection. The plan shall, at a minimum—

(1) Identify physical obstacles in the agency's facilities that limit the accessibility of its programs or activities to handicapped persons;

(2) Describe in detail the methods that will be used to make the facilities accessible;

(3) Specify the schedule for taking the steps necessary to achieve compliance with this section and, if the time period of the transition plan is longer than one year, identify steps that will be taken during each year of the transition period;

(4) Indicate the official responsible for implementation of the plan; and

(5) Identify the persons or groups with whose assistance the plan was prepared.

§ 39.151 Program accessibility: New construction and alterations.

Each building or part of a building that is constructed or altered by, on behalf of, or for the use of the agency shall be designed, constructed, or altered so as to be readily accessible to and usable by handicapped persons. The definitions, requirements, and standards of the Architectural Barriers Act, 42 U.S.C. 4151–4157, as established in 41 CFR 101–19.600 to 101.607, apply to buildings covered by this section.

§§ 39.152–39.159 [Reserved]

§ 39.160 Communications.

(a) The agency shall take appropriate steps to ensure effective communication with applicants, participants, personnel of other Federal entities, and members of the public.

(1) The agency shall furnish appropriate auxiliary aids where necessary to afford a handicapped person an equal opportunity to participate in, and enjoy the benefits of, a program or activity conducted by the agency.

(i) In determining what type of auxiliary aid is necessary, the agency shall give primary consideration to the requests of the handicapped person.

(ii) The agency need not provide individually prescribed devices, readers for personal use or study, or other devices of a personal nature.

(2) Where the agency communicates with applicants and beneficiaries by telephone, telecommunications devices for deaf persons (TDD's) or equally effective telecommunication systems shall be used.

(b) The agency shall ensure that interested persons, including persons with impaired vision or hearing, can obtain information as to the existence and location of accessible services, activities, and facilities.

(c) The agency shall provide signage at a primary entrance to each of its inaccessible facilities, directing users to a location at which they can obtain information about accessible facilities. The international symbol for accessibility shall be used at each primary entrance of an accessible facility.

(d) The agency shall take appropriate steps to provide handicapped persons with information regarding their section 504 rights under the agency's programs or activities.

(e) This section does not require the agency to take any action that it can demonstrate would result in a fundamental alteration in the nature of a program or activity or in undue financial and administrative burdens. If an action required to comply with this section would result in such an alteration or such burdens, the agency shall take any other action that would not result in such an alteration or such burdens but would nevertheless ensure that, to the maximum extent possible, handicapped persons receive the benefits and services of the program or activity.

§§ 39.161–39.169 [Reserved]

§ 39.170 Compliance procedures.

(a) *Applicability.* Except as provided in paragraph (b) of this section, this section applies to all allegations of discrimination on the basis of handicap in programs or activities conducted by the agency.

(b) *Employment complaints.* The agency shall process complaints alleging

violations of section 504 with respect to employment according to the procedures established in 29 CFR Part 1613 pursuant to section 501 of the Rehabilitation Act of 1973 (29 U.S.C. 791).

(c) *Responsible Official.* The Responsible Official shall coordinate implementation of this section.

(d) *Filing a complaint.*

(1) *Who may file.*

(i) Any person who believes that he or she or any specific class of persons has been subjected to discrimination prohibited by this part may file a complaint with the Official.

(ii) Before filing a complaint under this section, an inmate of a Federal penal institution must exhaust the Bureau of Prisons Administrative Remedy Procedure as set forth in 28 CFR Part 542.

(2) *Confidentiality.* The Official shall hold in confidence the identity of any person submitting a complaint, unless the person submits written authorization otherwise, and except to the extent necessary to carry out the purposes of this part, including the conduct of any investigation, hearing, or proceeding under this part.

(3) *When to file.* Complaints shall be filed within 180 days of the alleged act of discrimination, except that complaints by inmates of Federal penal institutions shall be filed within 180 days of the final administrative decision of the Bureau of Prisons under 28 CFR Part 542. The Official may extend this time limit for good cause shown. For purposes of determining when a complaint is timely filed under this subparagraph, a complaint mailed to the agency shall be deemed filed on the date it is postmarked. Any other complaint shall be deemed filed on the date it is received by the agency.

(4) *How to file.* Complaints may be delivered or mailed to the Attorney General, the Responsible Official, or agency officials. Complaints should be sent to the Director for Equal Employment Opportunity, U.S. Department of Justice, 10th and Pennsylvania Avenue, NW., Room 1232, Washington, D.C. 20530. If any agency official other than the Official receives a complaint, he or she shall forward the complaint to the Official immediately.

(e) *Notification to the Architectural and Transportation Barriers Compliance Board.* The agency shall promptly send to the Architectural and Transportation Barriers Compliance Board a copy of any complaint alleging that a building or facility that is subject to the Architectural Barriers Act of 1968, as amended (42 U.S.C. 4151–4157), or section 502 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 792), is not readily accessible to and usable to handicapped persons. The agency shall delete the identity of the complainant from the copy of the complaint.

(f) *Acceptance of complaint.*

(1) The Official shall accept a complete complaint that is filed in accordance with paragraph (c) of this section and over which the agency has jurisdiction. The Official shall notify the complainant and the respondent of receipt and acceptance of the complaint.

(2) If the Official receives a complaint that is not complete, he or she shall notify the complainant, within 30 days of receipt of the incomplete complaint, that additional information is needed. If the complainant fails to complete the complaint within 30 days of receipt of this notice, the Official shall dismiss the complaint without prejudice.

(3) If the Official receives a complaint over which the agency does not have jurisdiction, the Official shall promptly notify the complainant and shall make reasonable efforts to refer the complaint to the appropriate Government entity.

(g) *Investigation/Conciliation.*

(1) Within 180 days of the receipt of a complete complaint, the Official shall complete the investigation of the complaint, attempt informal resolution, and, if no informal resolution is achieved, issue a letter of preliminary findings.

(2) The Official may require agency employees to cooperate in the investigation and attempted resolution of complaints. Employees who are required by the Official to participate in any investigation under this section shall do so as part of their official duties and during the course of regular duty hours.

(3) The Official shall furnish the complainant and the respondent a copy of the investigative report promptly after receiving it from the investigator and provide the complainant and respondent with an opportunity for informal resolution of the complaint.

(4) If a complaint is resolved informally, the terms of the agreement shall be reduced to writing and made part of the complaint file, with a copy of the agreement provided to the complainant and respondent. The written agreement may include a finding on the issue of discrimination and shall describe any corrective action to which the complainant and respondent have agreed.

(h) *Preliminary findings.* If an informal resolution of the complaint is not reached, the Official shall, within 180 days of receipt of the complete complaint, notify the complainant, the respondent, and the Complaint Adjudication Officer of the results of the investigation in a letter sent by certified mail, return receipt requested, and containing—

(1) Preliminary findings of fact and conclusions of law;

(2) A description of a remedy for each violation found;

(3) A notice of the right of the complainant and respondent to appeal to the Complaint Adjudication Officer; and

(4) A notice of the right of the complainant and respondent to request a hearing.

(i) *Filing an appeal.*

(1) Notice of appeals to the Complainant Adjudication Officer, with or without a request for hearing, shall be filed by the complainant or the respondent with the Responsible Official within 30 days of receipt from the Official of the letter required by paragraph (h) of this section.

(2) If a timely appeal without a request for hearing is filed by a party—

(i) Any other party may file a written request for a hearing within the time limit specified in paragraph (i)(1) of this section or within 10 days of the date on which the first timely appeal without a request for hearing was filed, whichever is later.

(ii) If no party requests a hearing, the Responsible Official shall promptly transmit the notice of appeal and investigative record to the Complaint Adjudication Officer.

(3) If neither party files an appeal to the Complaint Adjudication Officer within the time prescribed in paragraph (i)(1) of this section, the letter of preliminary findings shall become the final agency decision on the complaint at the expiration of that time.

(j) *Acceptance of appeal.* The Complaint Adjudication Officer shall accept and process any timely appeal.

(k) *Hearing.*

(1) Upon a timely request for a hearing, the Responsible Official shall appoint an administrative law judge to conduct the hearing. The administrative law judge shall issue a notice to all parties specifying the date, time, and place of the scheduled hearing. The hearing shall be held no earlier than 15 days after the notice is issued and no later than 60 days after the request for a hearing is filed, unless all parties agree to a different date.

(2) The complainant and respondent shall be parties to the hearing. Any interested person or organization may petition to become a party or amicus curiae. The administrative law judge may, in his or her discretion, grant such a petition if, in his or her opinion, the petitioner has a legitimate interest in the

proceedings and the participation will not unduly delay the outcome and may contribute materially to the proper disposition of the proceedings.

(3) The hearing, decision, and any administrative review thereof shall be conducted in conformity with 5 U.S.C. 554–557 (sections 5–8 of the Administrative Procedure Act) and in accordance with such rules of procedure as are proper (and not inconsistent with this section) relating to the conduct of the hearing; giving of notices subsequent to those provided for in paragraph (h) of this section; taking of testimony, exhibits, arguments, and briefs; requests for findings; and other related matters. The parties shall be entitled to introduce all relevant evidence on the issues as stated in the notice for hearing or as determined by the administrative law judge.

(4) Technical rules of evidence shall not apply to hearings conducted pursuant to this paragraph, but rules or principles designed to assure production of the most credible evidence available and to subject testimony to cross-examination shall be applied by the administrative law judge whenever reasonably necessary. The administrative law judge may exclude irrelevant, immaterial, or unduly repetitious evidence. All documents and other evidence offered or taken for the record shall be open to examination by the parties and opportunity shall be given to refute facts and arguments advanced on either side of the issues. A transcript shall be made of the oral evidence except to the extent the substance thereof is stipulated for the record. All decisions shall be based upon the hearing record.

(5) The costs involved in the appearance of witnesses in the hearing shall be allocated as follows:

(i) Persons employed by the agency shall, upon request to the agency by the administrative law judge, be made available to participate in the hearing ans shall be on official duty status for this purpose. They shall not receive witness fees.

(ii) Employees of other Federal agencies called to testify at a hearing shall, at the request of the administrative law judge and with the approval of the employing agency, be on official duty status during any period of absence from normal duties caused by their testimony, and shall not receive witness fees.

(iii) The fees and expenses of other persons called to testify at a hearing shall be paid by the party requesting their appearance.

(iv) The administrative law judge may require the agency to pay travel expenses necessary for the complainant to attend the hearing.

(v) The respondent shall pay the required fees for the administrative law judge and court reporter, and all other expenses except those specifically allocated to the complainant, an intervening party, or an amicus curiae.

(6) The administrative law judge shall submit in writing proposed findings of fact, conclusions of law, and remedies to the Complaint Adjudication Officer within 30 days after receipt of the hearing transcripts, or within 30 days after the conclusion of the hearing if no transcript is made.

(l) *Decision.*

(1) The Complaint Adjudication Officer shall make the decision of the agency based on information in the complaint file and, if a hearing is held, on the hearing record. The decision shall be made within 60 days of receipt of the complaint file or hearing record. If the Complaint Adjudication Officer determines that he or she needs additional information from any party, he or she shall request the information and provide the other party or parties an opportunity to respond to that information. The Complaint Adjudication Officer shall have 60 days from receipt of the additional information to make the decision on the appeal. The Complaint Adjudication Officer shall transmit his or her decision by letter to the parties. The decision shall set forth the findings, remedial action required, and reasons for the decision. If the decision is based on a hearing record, it shall adopt, reject, or modify the decision that was recommended by the administrative law judge. If the decision is to reject or modify the recommended decision, the decision letter shall set forth in detail the specific reasons for the rejection or modification.

(2) Any respondent required to take action under the terms of the decision of the agency shall do so promptly. The Official or Complaint Adjudication Officer, as appropriate, may require periodic compliance reports specifying:

(i) The manner in which compliance with the provisions of the decision has been achieved;

(ii) The reasons any action required by the final decision has not yet been taken; and

(iii) The steps being taken to ensure full compliance.

§§ 39.171–39.999 [Reserved]

William French Smith,

Attorney General.

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federal register

Friday
December 16, 1983

Part VII

Department of Health and Human Services

Health Care Financing Administration

Medicare Program; Hospice Care; Final Rule

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: Final rule.

SUMMARY: These regulations 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 establish eligibility requirements and reimbursement standards and procedures, define covered services, and delineate the conditions a hospice must meet to be approved for participation in the Medicare program.

EFFECTIVE DATE: November 1, 1983.

FOR FURTHER INFORMATION CONTACT:

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

Conditions of Participation: Samuel Kidder (301) 597-5909; and

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 primarily 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 emotionally 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 when the individual's pain and symptoms must be closely monitored in order to be controlled, when medical intervention is required to control pain or palliate symptoms, or when the family needs a rest from the tedium and stress involved in caring for the individual (respite care).

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. Congress enacted this benefit with a "sunset" provision so the hospice benefit will be available only from November 1, 1983 through September 30, 1986.

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).

On August 22, 1983, we published a proposed rule (NPRM) regarding hospice care (48 FR 38146). The proposal elicited over 200 comments from the public. The provisions of the proposed rule, the major comments received, and the changes in response to those comments as well as additional changes are discussed below.

II. Provisions of the Proposed Rule

The August 22, 1983 publication proposed the implementation of the statutory inclusion of hospice care as a covered benefit under Medicare Part A. The NPRM proposed beneficiary eligibility requirements including the statutory requirement that the beneficiary be deemed to have waived most other Medicare benefits as a consequence of electing hospice care. The NPRM specified that the hospice benefit would cover the following items and services as hospice care: nursing care, medical social services, physicians' services, counseling services, short term inpatient care, medical appliances and supplies (including drugs and biologicals for palliation and management of symptoms), home health aide and homemaker services, and physical therapy, occupational therapy and speech-language pathology. It also specified proposed conditions a hospice must meet to be approved for participation in the Medicare program. Many of these conditions are required by statute. Others reflect conditions that we believe are necessary to assure the health and safety of hospice patients (for example, the requirement for a nurse coordinator to monitor the plan of care).

The NPRM proposed a reimbursement system for hospices based on prospectively determined rates. That is, hospices would be paid at a predetermined rate for each day on which a beneficiary is under the care of the hospice. Four rates were proposed based on the type and intensity of services furnished to the beneficiary on that day. The proposed rule also provided that the total Medicare payments made during a reporting period not exceed a "cap" amount. As specified by statute, the cap amount was based on the average amount that Medicare paid for traditional care during the last six months of life for Medicare beneficiaries who died of cancer. (Congress subsequently amended the statutory language regarding the cap amount. The new provisions of the statute relating to the cap amount and the manner in which it will be adjusted are discussed in section IV.D., below.) Also, in accordance with the statute, the NPRM provided that hospices may charge beneficiaries a coinsurance amount for each drug or biological and for each day of inpatient respite care.

The statute authorized the Secretary to designate hospice intermediaries and the NPRM designated one intermediary per State to serve freestanding hospices. The proposal specified that, generally, hospices that are based in another Medicare provider (for example, a hospital or home health agency) would be served by the intermediary servicing the parent provider. The exception would be a hospice whose parent provider deals directly with HCFA. In these cases, the hospice would use a contract intermediary designated by HCFA.

III. Discussion of Comments

We received over 200 comments on the proposed rule representing the views of hospices, hospitals, visiting nurses associations, home health agencies, national health organizations, State, county and city organizations, hospice volunteers and individuals. The comments are representative of a broad geographical range since they were received from 41 States and the District of Columbia. Generally, the commenters were pleased that Medicare coverage of hospice care had been enacted. The main comments received and our responses to those comments are grouped by subject area and are as follows:

A. General Comments

Comment: Several commenters observed that the 30-day comment period on the NPRM was not adequate.

Response: We would have permitted a longer comment period if time had

enabled us to do so. The need to publish a regulation effective November 1, 1983, made it necessary to provide for a shorter comment period. We note, however, that during the comment period, we received responses from over 200 commenters representing a broad spectrum of expertise relating to hospice care. Additionally, we consulted extensively in developing the proposed regulations.

B. Definitions

Comment: Many commenters objected to the proposed definition of a hospice employee (§ 418.3). That section defined an employee as an employee within the meaning of section 210(j) of the Act or a volunteer. If the hospice is a subdivision of an agency or organization, the hospice employee would be an employee of the agency or organization who is assigned and works "substantially full time" for the hospice unit. The commenters had primarily two objections to the definition. Several commenters suggested that only paid employees be included in the definition so that volunteer physicians could retain their ability to receive payment under Medicare Part B (as "attending physicians") for the medical care they provide to patients they refer to the hospice program and to prevent hospice liability for volunteers. Several commenters objected to the full time requirement and recommended that part time employment also be accepted.

Response: We will continue to consider a volunteer as an employee of the hospice because we believe that this provision enables hospices to meet various core services requirements (including the physician services requirements) by using unpaid volunteers. We do not believe that characterizing volunteers as employees, for purposes of these regulations, will in itself alter their legal relationships and responsibilities for other purposes. In addition, it prevents reimbursement in excess of the cap intended by Congress by requiring that all payments to these physicians must flow through the hospice as Part A hospice services and are subject to the hospice cap. We note, however, that the manner in which hospices will be reimbursed for physician services permits physicians who desire to donate some services and to receive payment for the others to do so. Under this benefit, the physician (who is considered an employee) may donate services he or she desires to donate (these services are considered volunteer services under the regulations) and may bill the hospice for the other services.

We agree that the deletion of the phrase "substantially full time" is appropriate and are revising the regulations to reflect that change. This change will allow parent providers the flexibility to allocate and rotate staff to hospice duties in an efficient manner. However, other requirements will continue to assure that staff be dedicated to hospice tasks and appropriately trained.

Comment: One commenter suggested that the proposed definition of a hospice (§ 418.3) as "* * * a public agency * * * that is primarily engaged in providing care to terminally ill individuals * * *" could lead to ambiguity and a dilution of the quality of care provided. The commenter recommended that the regulations state that the hospice be "exclusively" engaged in providing care to the terminally ill.

Response: The word "primarily" used in this definition was taken directly from the statutory language in section 1861(dd)(2) of the Act. We understand the commenter's concern but will adhere to the statutory language.

Comment: A number of commenters suggested that the term "social worker" (§ 418.3) should be redefined to require a master's degree in social work (MSW). The commenters indicate that an MSW is considered the appropriate credential by a number of national organizations and that many State licensure laws require an MSW as a condition for licensing social workers.

Response: We are retaining our definition as proposed. There is nothing in the regulation that prevents a hospice from engaging an individual with an MSW. Since the regulations require that all professional personnel employed by the hospice be licensed under State law (when there are State licensure requirements), higher State educational requirements would supersede our definition. We believe that the current definition enables hospices to meet appropriate Medicare requirements consistent with State law without preventing them from employing social workers who are suited to provide either medical social or counseling services to hospice inpatients.

C. Duration of Election

Comment: Several comments related to the hospice election periods contained in the proposed regulations. As specified in the NPRM, an election period is one of three periods for which an individual may elect to receive Medicare coverage of hospice care. The periods consist of two 90-day periods and one 30-day period that must be used in that order (§§ 418.3 and 418.24). One suggestion was that the hospice benefit be changed to include a total lifetime number of days rather than election periods. Another suggestion was that the 30-day period be used first and a final comment suggested that the patient should be able to choose whether a period is a 30 or 90-day period at the time he or she revokes the benefit.

Response: Both the length of the election periods and the sequence in which they must be used are statutory requirements (section 1812(a)(4) of the Act) and we have therefore left this provision unchanged.

Comment: A large number of commenters requested clarification of the professional and financial obligations of a hospice in relation to patients who have exhausted their 210 days of hospice entitlement (§ 418.24(c)). A variety of interpretations and suggestions were advanced.

Response: The law at section 1861(dd)(2)(D) requires that a hospice "not discontinue the hospice care it provides with respect to a patient because of the inability of a patient to pay for such care * * *." This requirement is also reflected in § 418.60 of the regulations, which says that a hospice may not discontinue or diminish care provided to an individual because of the individual's inability to pay. Thus, when a patient has exhausted Medicare hospice coverage, the hospice must continue to provide hospice services of the same intensity and frequency as if benefits had not been exhausted.

Comment: Several commenters suggested that provision should be made for hospices to discharge terminally ill patients from a hospice program when their physical condition or domestic circumstances are altered in such a way that they would no longer be considered acceptable patients under the hospice's admission criteria. For example, it was suggested that if a hospice has a patient who develops unexpectedly the need for long-term inpatient care or a patient who had upon admission but no longer has a primary caregiver, the hospice could discharge the patient.

Response: We do not agree with the view expressed by these commenters. A patient whose circumstances cause him or her to desire a different type of care may revoke a hospice election. However, a hospice may not discharge, at its discretion, a patient whose care promises to be costly or inconvenient. Once a hospice chooses to admit a Medicare beneficiary, it may not discharge the patient. If the hospice finds that the patient is no longer terminally ill, the hospice will be unable to recertify the patient and the patient

will no longer be eligible for the hospice benefit.

D. Certification of Terminal Illness

Comment: There were a number of comments regarding the requirement for a physician's certification of the terminal illness (§ 418.22). For the first 90-day period of hospice coverage, the proposed regulations required that the hospice obtain certifications from a hospice physician (the medical director or the physician member of the interdisciplinary group) and the individual's attending physician, if the individual has an attending physician. For the subsequent election periods, the proposed regulations required only that the hospice obtain certification from a hospice physician. In all instances, hospices are required to obtain the necessary certifications within 2 calendar days after initiating care. One group of commenters suggested that the 2-day period be expanded or that telephone certifications be accepted and later confirmed in writing or that only one of the two required certifications be within 2 days with the other one accepted later. The other group of commenters suggested that the attending physician also be required to perform recertifications at the start of the subsequent election periods. Their rationale was that attending physicians would help assure the quality of care.

Response: The requirement that certification be accomplished within 2 days of admission is a statutory requirement (section 1814(a)(8) of the Act) and we cannot change it. We believe that a written certification is the only true assurance that the patient's condition has been assessed at or before the time of admission to a hospice program and we have left this requirement unchanged as well. Proper and timely assessment of a patient's condition is of critical importance both to the hospice, which becomes responsible for care of the patient, and to the patient, who must have a sound basis for choosing palliative rather than curative care. We have not accepted the suggestion that the attending physician be required to make the recertifications required by the law because the law clearly distinguishes between the initial certification and recertifications and only requires the attending physician to participate in the initial certification. We do not believe that certifications and recertifications relate to quality assurance. They are simply determinations as to the patient's medical prognosis, not the plan of care or the type of treatment actually received.

E. Election Statement

Comment: We received a large number of comments concerning the proposal to require the terminally ill individual wishing to receive hospice care under the Medicare hospice benefit to personally sign an election statement (§§ 418.24 and 418.26). Almost without exception, the commenters opposed the requirement. As proposed in the NPRM, the election statement would be the means by which an individual elects to receive hospice care. It includes the individual's acknowledgment of terminal illness and the waiver of certain other Medicare benefits. The commenters felt that the proposal discriminated against those terminally ill individuals who (often because of their terminal illness) are mentally incapable of acknowledging these factors or physically unable to sign an election statement, as well as discriminating against the families of these individuals. We received various suggested alternatives from commenters including the recommendations that we permit the following individuals to sign the election statement on behalf of the terminally ill individual: family members, a significant other, a legal guardian, an individual with the power of attorney, or an individual designated by a living will (some State laws recognize these documents as an acceptable indication of an incompetent patient's preference). Other commenters suggested that we also permit representatives to revoke a hospice election when they believe the patient requires curative care.

Response: We recognize that there is a need to permit some flexibility in the proposed requirement to assure access to hospice services by all individuals who need them. However, we continue to be concerned that this critical choice not be made on a patient's behalf without safeguards to his or her right to continued Medicare coverage of curative care. In the final regulations we are indicating that when a patient is mentally unable to make the decision concerning a hospice election statement, a change of election or a revocation, someone other than the patient may do so when authorized in accordance with State law.

Similarly, in cases where a physical disability (for example, blindness or stroke) prevents a competent patient from writing a signature, the decision to elect hospice may be written by someone else to reflect the patient's decision in a manner consistent with State law.

Comment: Many commenters suggested that the requirements governing the election be revised to avoid the current stipulation that the individual acknowledge his or her terminal illness (§ 418.26). A frequently suggested alternative was that we require the patient to acknowledge that he or she has been given a full understanding of the nature of hospice care.

Response: We have accepted these comments and made an appropriate change in this section of the regulations. We have done so because we understand that hospice care is a process by which a patient, who knows and accepts the nature of hospice care at the beginning of a stay, comes to accept the implications associated with it. We agree that it may, under certain circumstances, be inappropriate to require so explicit an acknowledgement of his or her impending death at the time of election. However, we expect that the full understanding of the nature of hospice care provided to the beneficiary or representative by the hospice will include an explanation that in electing the hospice benefit, palliative care is being elected in lieu of curative care.

Comment: Many commenters asked questions and made suggestions concerning the provision under which the patient who elects hospice care waives coverage under Medicare for hospice care not provided by or through the hospice and any other care related to the terminal condition (§ 418.24(e)). The commenters suggested a more detailed definition of what constitutes care for a patient's terminal illness or related conditions (which is the responsibility of the hospice) and what constitutes care for unrelated conditions (for which out-of-hospice Medicare payment may be made). Some of these commenters suggested that the statutory exception permitting continued out-of-hospice Medicare coverage in "exceptional and unusual" circumstances could be used by HCFA as a means of permitting payment for ambulance services or certain potentially costly medical services needed by a terminally ill patient for the palliation or management of his or her symptoms.

Response: As noted in the proposed regulation, we believe that the unique physical condition of each terminally ill individual makes it necessary for these decisions to be made on a case by case basis. It is our general view that the waiver required by the law is a broad one and that hospices are required to provide virtually all the care that is needed by terminally ill patients. The example that we provided in the proposed regulation of a hospice's

responsibility to treat a patient for pneumonia which developed as a result of his or her weakened condition reflects this view.

We note that payment for services, including necessary physician services, is made to the hospice for all patients; and we believe that the cost experience of the HCFA demonstration projects shows that these related services may be provided within the amount established by Congress as the cap.

We recognize that additional claims processing guidelines will be needed to assure that Medicare intermediaries understand the nature of hospice coverage and are able to process out-of-hospice claims properly. We will be preparing those guidelines and issuing them to the intermediaries in the near future. We do not believe that these operational instructions are appropriately a part of these regulations.

Finally, we have not received any suggestions for identifying "exceptional or unusual circumstances" that warranted the inclusion of a specific provision in the regulations to accommodate them. Most of the comments that were made attempted to suggest this exception as a means of routinely providing non-hospice Medicare financing for the expense of costly services needed by hospice patients and we do not view this as an appropriate interpretation of the law. We agree with the commenter who suggested that this provision should not be implemented until we are able to identify circumstances appropriate to the waiver.

F. Conditions of Participation

1. *General provisions (§ 418.50).*

Comment: Some commenters noted that the proposed regulations omitted the Federal requirements relating to disclosure of ownership information to which hospices, as providers within the meaning of the Medicare law, are subject.

Response: We are including in the final regulations the requirement that hospices comply with the disclosure of ownership requirements specified in 42 CFR 420.206.

Comment: Almost all of the commenters who addressed the standard regarding required services suggested that the language mandating 24-hour a day services be modified to indicate specific services which must always be available on that basis. They noted that some of the services, such as physical therapy, and occupational therapy and bereavement counseling need not be routinely made available on a 24-hour a day basis because they may generally be provided during the usual work day with no disadvantage to the patient.

Response: Although the statute requires that a hospice make all covered services available as needed on a 24-hour basis (section 1861(dd)(2)(A)(i) of the Act), we agree that the availability of certain items is especially critical and will modify the regulations at § 418.50(b) to enumerate the basic services (nursing services, physician services, and drugs and biologicals) that a hospice must routinely make available on a 24-hour a day basis. We expect that the physician available would be empowered to authorize provision of services not specified in the plan of care (for example, provision of emergency services or an unanticipated admission for inpatient care). We will continue to require that a hospice provide all other services on a 24-hour basis to the extent necessary to meet the needs of its patients but recognize that this may not be a frequent need.

2. *Governing body (§ 418.52).*

Comment: A number of commenters suggested that the requirements for the governing body include a requirement that the body designate an administrator or other individual to be responsible for the day to day management of the hospice program.

Response: We believe that the suggestion regarding the designation of an individual to be responsible for the day to day management of the hospice is useful and will incorporate the requirement in the final regulations at § 418.52. We note that this individual need not be a physician.

3. *Medical director (§ 418.54).*

Comment: Several commenters suggested that the proposed regulations assigning responsibility for all of the hospice's patient care program to the medical director were inappropriate. It was noted that a physician is needed primarily for the medical component of a hospice program not the administrative component, and that medical direction should be limited to this area.

Response: We agree with this suggestion and will modify the regulations to require that the medical director must assume overall responsibility for the medical aspects of a hospice's program. We note that this change is consistent with the addition of a requirement that the governing body identify an individual with overall responsibility for day to day administrative management of the hospice program.

4. *Professional management (§ 418.56).*

Comment: Many commenters expressed the opinion that the proposed requirements governing professional management responsibility for arranged-for services were overly prescriptive. Some commenters even suggested that formal agreements should not be required and that informal arrangements between hospices and institutions, or other providers should be accepted. The major portion of the comments related specifically to inpatient care and dealt with the requirement for a written agreement (which many commenters did not favor), and the requirement that the hospice's plan of care govern the services provided to the individual. Concerns were expressed that situations in which a hospice plan of care and an individual's attending physician called for different approaches to medical management would require that an inpatient provider make a choice that might subject it to malpractice liability. Some hospices also expressed the concern that detailed written agreements could subject them to liability when inappropriate care was furnished in the facility. Finally, comments were received that suggested that it is not necessary to require the hospice to obtain the entire inpatient medical record and that a discharge summary would be adequate.

Response: We agree that the proposed regulations required some changes. We have reorganized the section concerning written agreements (§ 418.56(b)) to make it clear that *all* written agreements must contain basic provisions that assure that the policies of the hospice and the patient's plan of care are carried out. Despite the comments we have received concerning the traditional medical autonomy of the inpatient provider, we believe it is clearly the intent of the law that hospice patients be treated exclusively in the way prescribed in the plan of care established by the hospice interdisciplinary group.

We are also revising the proposed standard relating to professional management responsibility (§ 418.56(c)) to require that arranged-for services be consistent with the plan of care. We are incorporating the proposed requirement for documenting that services were provided pursuant to the agreement and for appropriate licensed personnel (in the NPRM, § 418.56(e) (2) and (3)) in the standard for a written agreement at § 418.56(b) and will make it applicable to all written agreements instead of applicable only to agreements regarding inpatient care. We are deleting several portions of the proposed section regarding inpatient care (§ 418.56(e)) and are making two other substantive changes. We will modify the requirement that the hospice medical records contain a record of all inpatient

services and events to permit the hospice (at its discretion) to require only a discharge summary from the inpatient provider. We will do this because we recognize that a hospice may wish to evaluate the patient's treatment continuously during an inpatient stay by means of direct supervision and independent written records and may not require detailed medical records from the provider (containing nursing notes, medication orders, etc.) in order to complete the patient's file. Hospices are still required to maintain a complete medical record, however, and must obtain the inpatient provider's records if they do not maintain records themselves. We are also modifying the requirement that makes the hospice responsible for "orientation and continuing education" of the inpatient provider's hospice staff to make it clear that we intend the hospice to be responsible for "appropriate hospice care training" of staff and not routine continuing medical education.

We believe that the liability issue raised by the commenters will not result in the difficulties anticipated. The hospice plan of care, established by the interdisciplinary group, must precede the provision of any care. While an attending physician may participate in the development of this plan and provide care under it, we expect that the hospice interdisciplinary group, the attending physician, and the patient will have to reach an agreement regarding the treatment before services are provided. If a patient prefers the type of care proposed by the attending physician and the hospice's interdisciplinary group proposes a different mode of care, the patient may revoke the hospice election and accept treatment from the physician outside the hospice benefit. Alternatively, the patient may choose to remain in the hospice program and refuse the suggestions of his or her attending physician. In either event, we believe that the inpatient provider will be subject to only one set of orders and will not be routinely required to mediate conflicts on this issue.

5. *Plan of care (§ 418.58).*

Comment: Commenters on the section relating to the plan of care made two basic points. One was that we ought to permit some latitude in the section governing the establishment of the plan of care so that the medical director could be represented by a designee (e.g., the physician member of the interdisciplinary group). Several commenters also attempted to deal with the need for a plan of care before providing care by suggesting that the regulations should provide for a "standard" or temporary plan of care during the early period of hospice care.

Response: We accepted the comment concerning the use of a designee by the medical director and the regulations will reflect this change. We would note that a plan of care is a changing document, however, and that a hospice may choose to develop a relatively brief plan of care upon admission and revise and update it as it gains further information about the patient's needs. Therefore, we see no need to provide for a separate temporary or provisional plan of care. On the other hand, we believe that the law clearly intends that the plan of care for the individual reflect his or her individual needs and we do not believe it appropriate that hospices use a "standard" or pro forma plan of care. Thus, we have rejected this suggestion.

6. *Continuation of care (§ 418.60).*

Comment: A number of commenters noted that the requirement for a hospice to continue to provide care to a patient regardless of his or her ability to pay could subject a hospice to unanticipated financial liability. They suggested that this requirement be deleted or that it apply only to Medicare beneficiaries.

Response: This is a statutory requirement for participation as a Medicare hospice and cannot be deleted. However, in our review of this issue, we have determined, based on the legislative history, that it applies only to Medicare beneficiaries.

7. *Informed consent (§ 418.62).*

Comment: Commenters on the informed consent requirement suggested that provision should be made for consent by an individual other than the patient in cases where the patient is unable to give it. Some commenters suggested that the informed consent instrument used in HCFA's hospice demonstration projects should be used for this purpose.

Response: The proposed requirement was written to be consistent with the proposed policy that an election be made only by the patient. As discussed in section III.E., we are modifying the regulations to permit someone authorized by State law to execute a hospice election. Therefore, we are accepting these comments and are modifying this requirement so that it now mandates only that a hospice have obtained an informed consent document for every patient. We have not introduced any specific requirements as to the content or format of this document because we believe that a hospice should be able to develop a document that embodies its own philosophy and approach to treatment.

8. *In-service training (§ 418.64).*

Comment: Comments on the proposed inservice training requirement dealt with two issues. First, it was suggested that the requirement should also apply to contract staff. Second, if was suggested that a more comprehensive requirement be developed.

Response: We note that the proposed section on professional management responsibility required that a hospice provide necessary hospice care training to contract staff in the case of inpatient services. We believe that other contract staff, because of the nature of their skills, will not require specific hospice care training beyond the instruction inherent in professional management of their services by the hospice. We also believe that the other requirements of these regulations, including the requirements for quality assurance, will operate to produce the necessary quality of care. Therefore, we have not accepted the suggestion for a more comprehensive requirement. In reviewing the requirement, however, we noted that the current language, which includes a requirement for continuing education, required clarification. Our intention was to include a provision that required the hospice to assure that its staff is trained adequately in the provision of hospice care. Therefore, we have deleted the words "continuing education," which have a generally accepted connotation that is much broader than the training we intended.

9. *Quality assurance (§ 418.66).*

Comment: Commenters on the quality assurance requirement suggested that the section be augmented with more detailed utilization review provisions. A few commenters suggested that the requirements contained in Medicare's home health conditions of participation be used as a model. Several commenters suggested that an outside party should be involved in the activity. There were also some technical editorial suggestions.

Response: We will make several changes in this section to streamline the condition and to correct what were essentially drafting errors. We have not accepted the suggestions for more detailed requirements or for the involvement of an outside party. We believe that the nature of hospice care under this benefit, which relies on the interdisciplinary group for the development of a comprehensive plan of care, supervision or provision of the care, and continous evaluation and revision of the plan of care, is one which inherently involves continuous peer review. It is the lack of such an integrated approach in home health care

that necessitates the more formal medical record review requirements contained in the conditions of participation for home health agencies. We believe that the strong statutory requirements which make the interdisciplinary group accountable for designing and reevaluating the plan of care will achieve the result we anticipate. We also believe that the safeguards built into the survey and certification procedures, as well as into the claims review process, are an adequate external measure of the hospice's quality assurance mechanism.

10. *Interdisciplinary group (§ 418.88).*

Comment: Commenters on the interdisciplinary group provision made a number of suggestions for expanding group membership by adding specialized medical personnel, such as speech language pathologists and pharmacists. It was also suggested that the attending physician should be permitted to be the physician member of the group. Finally, it was suggested that the proposed section should be amended to permit a hospice to have more than one interdisciplinary group.

Response: One basic theme underlying the comments was that participation in the activities of the interdisciplinary group should not be restricted by the regulations to the four employee professionals enumerated in the regulations and the law. We agree with this concept and will modify the regulations so that a hospice may include other individuals as well as the employee physician, nurse, social worker, and counselor explicitly required by the law. Thus, a hospice may involve as many members of the care team as it wishes in the group's activities. An attending physician may also participate in the activities of this group; however, unless that physician is also an employee of the hospice (salaried or volunteer), the law does not permit him to serve as the sole physician member of the group. Finally, we will change the language of the regulations to permit the existence of more than one interdisciplinary group for most of the purposes required in the statute. We recognize that the size of the hospice and the number and character of its patients may make more than one group advisable. However since section 1862(dd)(2)(B)(iii) also gives the group a policymaking role not susceptible to fragmentation, we have required that a hospice with more than one group designate a specific group to "establish policies governing such care and services."

11. *Volunteers (§ 418.70).*

Comment: We received a variety of comments on volunteers, many of them going beyond the contents of the regulations to discuss philosophical or other considerations. The commenters were divided on the main issue: whether to set a numerical standard for volunteers. There was, however, a clear preference for avoiding any numerical standard and favoring more subjective measures of performance. It was also suggested that professional volunteers be required to have appropriate licensure and that the designation of a volunteer coordinator be required. Some commenters opposed the basic statutory requirements for the recruitment and use of volunteers, the maintenance of volunteer effort, and the documentation of savings.

Response: We are unable to adopt the suggestions that statutory requirements be deleted. We will however, include a requirement for the designation by the hospice of a volunteer supervisor. We note that, because volunteers are considered employees within the context of the hospice regulation, the licensure requirements in § 418.72(b) also apply to volunteers. We carefully considered all the comments concerning the use of a numerical standard for volunteer effort and concluded that it is appropriate for us to include one in the final regulation. Accordingly, we are requiring that a hospice must document and maintain a volunteer staff sufficient to provide administrative or direct patient care in an amount that, at a minimum, equals 5 percent of the total patient care hours by all paid hospice employees and contract staff. Administrative support in this context means administrative support of the patient care activities of the hospice (e.g., clerical duties in the offices of the hospice) and not more general support activities (e.g., participation in hospice fund raising activities). We will adopt this standard for three reasons. First, Congress intended minimum participation requirements for volunteers. Second, our examination of preliminary data on the use of volunteers in the HCFA hospice demonstration project persuades us that this is an achievable goal for all types of hospices. Third, hospice groups have indicated that a 5 percent standard would be acceptable. We note that documentation indicating that the hospice meets this standard will be required at the time of the survey to determine that a hospice meets the conditions of participation. Additionally, we will make several editorial changes to simplify and clarify the other provisions of this section.

12. *Central clinical records (§ 418.74).*

Comment: Commenters suggested that the provision for clinical records contain a further requirement for patient consent regarding the release of medical information.

Response: The proposed regulations required that the hospice "safeguard the clinical record against loss, destruction, and unauthorized use." We believe that this requirement is adequate and have introduced no further requirement.

13. *Core services (§§ 418.80–418.88).*

Comment: A great many commenters discussed the proposed requirement that core services, including nursing care, be provided directly by hospice employees virtually full time. Primarily, these commenters argued that this requirement will force some coalition hospices to change their method of operation and that it could make it difficult for some organizations to become hospices. One commenter specifically stated that the requirement for direct provision of core services by employees could present problems for health maintenance organizations which obtain all physican care under arrangements with other organizations. The commenter suggested that an exception be made to permit this practice. Other commenters argued that the requirement for directly providing core services would duplicate existing nursing staffing requirements at home health agencies. Some commenters, on the other hand, supported the requirement as the means of assuring that critical services are provided by persons trained and dedicated to hospice care.

Response: Section 1861(dd)(2)(A)(ii)(I) of the Act, in referring to core services, states that a hospice "must routinely provide directly substantially all of each of the [core] services." We do not believe that this statutory requirement is susceptible to a broader interpretation than we have given to it. We note that the regulations do provide for the use of contract staff to perform core services when peak patient loads or other extraordinary circumstances cause the hospice's staffing needs to exceed normal staffing levels. Beyond this distinction, we believe a further relaxation of the employment requirement would make it impossible to draw a meaningful distinction between core services and arranged for services, over which the statute requires that the hospice exert professional management responsibility. Accordingly, we are not modifying the provisions in the proposed regulation that described it. We note that there have been several bills introduced in Congress to modify this provision. If the law is changed, we will, of course, modify these regulations as necessary.

14. *Medical social services (§ 418.84).*

Comment: A number of commenters on the condition of participation regarding medical social services suggested that the requirement for physician direction should be dropped.

Response: Physician direction of medical social services is a statutory requirement (section 1861 (dd)(1)(C) of the Act) and we are therefore retaining it.

15. *Physician services (§ 418.86).*

Comment: A number of commenters on the condition relating to physician services expressed concern about the role of the attending physician in providing care to the hospice patient. They were concerned that the proposed requirement that the hospice provide directly enough physician services to meet the "general medical needs of the patients" would lead to the exclusion of attending physicians or to the duplication of their services.

Response: We did not intend the result suggested by the commenters and are revising the regulations to indicate that the requirement for the hospice to provide care for the general medical needs of the hospice patients relates to services that are not provided by the patient's attending physician. We note, also, that the changes we are making in the section relating to the interdisciplinary group (see number 10, § 418.68, above) will make it clear that the attending physician may be permitted to participate in the deliberations of the group over the establishment, evaluation, and alteration of the patient's plan of care.

16. *Counseling services (§ 418.88).*

Comment: A number of commenters suggested that more detailed credentialing requirements be incorporated into the condition for counseling. For example, we have received suggestions that counseling, in certain cases, should be permitted only when provided by individuals with master's or doctor's degrees and with specialized training in various disciplines. We also received a suggestion for revising the definition of dietary counseling and a suggestion that we specify that we explicitly recognize the counseling provided by other members of the interdisciplinary group.

Response: We are adding a standard that specifies that counseling may also be provided by other members of the interdisciplinary group as well as other qualified professionals as determined by the hospice. We are not, however, establishing further requirements relating to training or certification. We believe that it was the intent of Congress to make use of the many valuable counseling services now available to the terminally ill, including clergymen and lay persons with appropriate experience or training. Accordingly, we prefer at this point to rely on the hospice to recruit counselors who have appropriate education or experience, to provide them with any additional training that may be necessary, and to use them as it deems appropriate. We have not revised the dietary counseling standard because it already requires the use of a qualified individual.

17. *Home health aide and homemaker services (§ 418.94).*

Comment: Commenters suggested that the requirement for biweekly supervisory visits from a registered nurse be deleted because it is unnecessary in view of the interdisciplinary group's continuous involvement in monitoring the care provided to the patient. Other commenters suggested making home health aide and homemaker services mandatory and also suggested a more detailed specification of the duties.

Response: We are clarifying the requirement for biweekly visits to indicate that these need not be visits for the sole purpose of supervising the home health aides. We note that the duties of home health aides are already detailed in the regulations which are cross-referenced and we do not believe further enumeration is necessary. In the case of homemaker services, the statute does not require an enumeration of duties or a training program. We believe that the hospice may appropriately determine the duties and that it is not necessary to specify these nonmedical tasks in these regulations. Finally, we note that home health aide and homemaker services are a required hospice service whenever they are needed by a hospice patient.

18. *Medical supplies (§ 418.96).*

Comment: Most of the comments on the condition of participation governing medical supplies and drugs noted that the requirements included in § 418.96 (a) through (e) were explicitly suited to inpatient settings and could not be used in the home setting. Many commenters noted that members of a patient's family were not among the individuals authorized to administer drugs and suggested that family members be included.

Response: We agree with the first comment and we are revising this section to remove the exclusively institutional requirements. However, we are retaining the general requirements that accepted standards of practice be observed and the requirements regarding the administration of pharmaceuticals. As the commenters noted, the standard that we proposed regarding the administration of drugs did not permit administration by family members. The standard, as written, had applied to an institutional setting. We are adding to the list of individuals who may administer pharmaceuticals any other individual in accordance with applicable State and local laws. We have also required that these individuals and each pharmaceutical they are authorized to administer must be specified in the patient's plan of care. In addition, we are specifying that the hospice must have a policy for the disposal of controlled drugs maintained in a patient's home when those drugs are no longer needed by the patient. We are reluctant to mandate by Federal regulations the removal of drugs that are the property of an individual from the home for purposes of disposal, but under the revised standard each hospice is free to establish appropriate protocols. In the inpatient setting, the appropriate pharmacy requirements in the hospital, skilled nursing facility (SNF), or intermediate care facility (ICF) are applicable or, in the case of a freestanding hospice, the requirements contained at § 418.100(l) apply.

19. *Short term inpatient care (§ 418.98).*

Comment: Most of the commenters addressing the condition of participation relating to short term inpatient care opposed the statutory requirement that a hospice maintain for its Medicare patients, in the aggregate, a ratio of no more than 20 percent of its days of care on an inpatient basis. Other commenters asserted that the freestanding hospice requirements should be based on the SNF conditions of participation and that the use of the less stringent ICF conditions should be prohibited for hospice inpatient care. Individual commenters suggested various ways to tighten the standards.

Response: We were unable to consider a change in the requirement relating to the use of a ratio for inpatient services for Medicare patients because it is explicitly contained in the statute (section 1861 (dd)(2)(A)(iii) of the Act). We agree with many of the commenters that an ICF (possibly even an ICF that meets the additional nursing requirements contained in § 418.100) may not be the appropriate site for furnishing much of the short term inpatient care hospice patients require. We believe, however, that some patients may well be appropriately served in this setting. For example, respite care provided in a facility that is certified as an ICF and meets the additional requirements we are establishing may be appropriate for certain patients. We

note that a hospice is required to provide short term inpatient care that meets all the needs of its patients and it appears to us that a hospice may well need to make additional arrangements with facilities capable of providing a more intense level of skilled care in order to fully meet the needs of its patients. We are accommodating the concerns expressed by the commenters in two ways. First, we are modifying the condition of participation for freestanding hospices providing inpatient care directly by strengthening a number of the standards. We are adding new material concerning linens, pharmacy services, and staffing. We believe the changes we are making will meet the concerns of the commenters who suggested augmenting the inpatient care standards. We are also modifying the short term inpatient care condition of participation to say explicitly that only respite care may be provided in an ICF and that general inpatient care must be provided in a hospital, an SNF, or a freestanding hospice that meets the strengthened conditions.

20. *Freestanding hospices providing inpatient care directly (§ 418.100).*

Comment: Commenters addressing the freestanding hospice conditions of participation suggested that the registered nurse supervision requirement was confusing and duplicative in view of the general requirement for 24-hour staffing by a registered nurse. They also suggested that the requirements governing patient areas should be modified to avoid the implication that structural modifications would be required to meet the standard. There were several suggestions for minor revisions in the standard including a recommendation that we add a requirement that there be areas for food preparation. Finally, it was suggested that a number of requirements now part of the SNF conditions of participation be added.

Response: We agree that the supervision requirement is redundant in conjunction with the nurse staffing requirement and are therefore deleting it. We are also modifying the standard on patient areas to eliminate the requirement that the areas be "designated" as a means of assuring that the requirement does not entail structural modification. We are not adding additional patient area requirements, as some commenters suggested, because we do not believe that they could be included without special construction. As we noted in connection with the hospice short term inpatient care requirement (number 19, above), we are strengthening the standards as recommended by some commenters.

G. Approval of a Hospice Program

Comment: Several commenters suggested that HCFA should seriously consider exercising its authority to deem compliance with the Medicare conditions of participation for hospices accredited by the Joint Commission on the Accreditation of Hospitals (JCAH). One comment opposed deeming.

Response: At this point, the JCAH has not requested that we consider deeming compliance with Medicare standards for its accredited members. If such a proposal is made, it will be carefully evaluated. It is clear, however, that for the initial surveys, there is no alternative but to use state surveyors to apply the conditions of participation contained in these regulations.

H. Special Coverage Requirements

1. *Continuous home care.*

Comment: Many of the commenters asserted that the requirement (§ 418.204) that continuous home care be predominantly nursing care is inconsistent with current hospice practices, that involve a more intensive use of home health aide and homemaker services with nursing supervision. Suggestions were made for describing this benefit in terms that would embrace this type of care.

Response: We believe that these comments stem from some misunderstanding of the method by which HCFA has grouped hospice services for purposes of constructing the payment rates. Care of the type described by the commenters is routine home care within the meaning of the regulations and the cost of providing it is built into the payment rates, as was explained in the preamble of the proposed rule. As described in the regulations, continuous home care is care furnished during brief periods of crisis and only as necessary to maintain the terminally ill patient at home. Thus, we believe that the requirement for predominately nursing care is necessary to ensure quality care during these periods of crisis. Home health aide and homemaker services or both may also be provided as necessary.

2. *Bereavement counseling.*

Comment: Commenters addressing bereavement counseling primarily asserted that payment should be made for it. Other commenters objected to the mention of clergy and suggested that bereavement counseling should not be treated separately as a service but should be authorized to be provided by other hospice staff.

Response: The statutory requirement that payment not be made for bereavement counseling does not permit us to consider the major suggestion. With respect to clergy, we note that the regulations do not require that clergymen must perform this function; bereavement counseling may be provided under these regulations by any hospice employee who is qualified to do so.

I. Reimbursement

1. *Use of prospective payment.*

Comment: A substantial number of commenters objected to the proposal to use the cost-related prospective payment method described in the NPRM. That payment method included four predetermined rates for each day a qualified Medicare beneficiary is in the care of the hospice. Specifically, the commenters objected to our use of data from HCFA's hospice demonstration in establishing those rates. The commenters believe that the data are inadequate because the 26 demonstration hospices are not representative of the organizations that will participate when the benefit is effective.

Response: We believe that the data from HCFA's hospice demonstration, used in conjunction with other Medicare program data, provides an adequate basis for the development of a prospective payment system. We further believe the rates are adequate to provide care in accordance with patients' needs and that hospices will not eliminate necessary services or refuse to serve patients.

Comment: Many commenters objected to the proposed prospective payment method because they believe that it places the hospice at an unnecessarily high degree of risk during the initial years of the benefit.

Response: We share the commenters' concerns that hospices not be disadvantaged by the methodology. However, we are satisfied that the system results in an equitable level of payment for hospice care. Moreover, the use of prospective payment incorporates incentives for hospices to operate in a cost-efficient manner, since the level of payment is known in advance. This should facilitate financial planning and budgeting.

Comment: Many commenters believe that the prospective methodology will encourage hospices to avoid treatment for those patients whose care might be complicated or costly and will provide an incentive for insufficient provision of care.

Response: We believe the rates are adequate to provide care in accordance with patients' needs and that the conditions of participation and other program safeguards will ensure that hospices will not eliminate necessary services or refuse to serve patients.

Comment: A substantial number of commenters objected to the use of the prospective payment methodology because they believe the proposal violated the Congressional intent that payment be cost-related.

Response: As explained in the preamble to the proposed regulations, the statute at section 1814(i)(1) of the Act grants the Secretary broad authority in calculating the amount of Medicare reimbursement for hospice care. A cost-related prospective payment system is consistent with this grant of authority. We note that HCFA has established prospective payment methods for other services, such as renal dialysis, based upon statutory language similar to that contained in the hospice legislation. We also note that the General Accounting Office, in a letter report dated July 12, 1983, concluded that:

> Under the law the Secretary of HHS has authority to implement a prospective payment system. Although the inclusion of a provision requiring a study of the feasibility and advisability of prospective reimbursement for hospice care indicates that the Congress did not expect HHS to implement a prospective reimbursement system immediately, the law does not preclude it from doing so. Furthermore, including the study requirements indicates that the Congress was considering moving toward adoption of a prospective reimbursement system.

Comment: Many of the commenters who opposed the prospective method urged that HCFA use a reasonable cost method of payment with suitable retroactive adjustment for payments during the initial years of the hospice benefit. This would enable HCFA to develop an adequate base for establishing a prospective payment system in future years.

Response: We are concerned that the use of a reasonable cost method of payment, even on an interim basis, would encourage the proliferation of hospice costs without regard to effectiveness and efficiency. Moreover, the use of a cost reimbursement system would permit the early inefficiencies of this new benefit to become embedded in the rate structure. Therefore, in the final regulation, we are adopting the prospective method of payment set out in the proposed rule. We believe, all things considered, that the method is the most appropriate of the methods for payment of hospice care that could be established within the constraints of available data and knowledge. While it would obviously be better to have a more developed data base, we continue to believe the demonstration data are suitable.

Comment: One commenter suggested HCFA reconsider the use of the prospective capitation system that was discussed in the NPRM. The commenter believes that a capitation system is consistent with the cap, whereas the prospective system we proposed is not.

Response: As stated in the preamble to the proposed regulation, we believe that a capitation payment method provides hospices with the strongest possible incentives to treat only those patients whose death could be expected to occur well within 6 months, perhaps within days. Not only would this increase the marginal cost of the hospice benefit, it would also contradict the philosophy of hospice care.

Comment: Several commenters supported the idea of prospective payment for hospice care, but suggested that HCFA develop a system of payment for inpatient hospital care based on diagnosis-related groups (DRGs).

Response: We are not accepting this comment at this time. It would involve the classification of all terminally ill patients into one or more DRGs (consistent with the nature of their illness and the relative resource consumption associated with hospice treatment).

HCFA will be collecting appropriate data from the outset of the implementation of the hospice benefit and plans to evaluate the financing of this benefit through a DRG system.

2. *Rate categories.*

The proposed regulations described four levels of care for which separate payment rates would be established. These proposed rates were as follows:

- Routine home care
- Continuous home care
- Inpatient respite care
- General inpatient care

A significant number of general comments on the levels of the rates were received. These comments, for the most part, described one or more of the proposed rates as inadequate. However, those comments did not contain factual material to demonstrate why the rates were insufficient, or to support proposed rates that would be sufficient. More specific comments on the rate structure and levels are discussed in the section dealing with rate determinations (sections III.I.3. below).

Comment: A number of comments were received regarding the rate categories. The majority of these commenters suggested the inclusion of an additional category for home respite care. Some commenters suggested that the rate be established at an amount between the routine and continuous care amounts.

Response: There is nothing in the statute or regulations that precludes a hospice from providing respite care in the patient's home. We did not develop a separate rate for this level of care because the data from the HCFA demonstration project indicate that the cost of home respite very closely approximates the routine home care costs (that are reflected in the current routine home care rate). Thus, most home respite would be provided and billed for as routine home care. In the event that the patient's medical condition requires a significant amount of skilled care, respite care could be provided at the continuous home care rate.

We also considered whether a factor should be built into the home care rates to compensate for added costs incurred by hospices in treating patients who do not have a person in the home to assist with their care. We have not made an adjustment because we understand that hospices generally require a primary caregiver as a prerequisite for admission to the program because such individuals are usually necessary if a patient is to remain in the home. The statutory constraints on provision of continuous home care and inpatient care, as well as the cap, are clear indications that hospices are not expected to provide the types of services associated with primary caregivers but rather, that they are expected to supplement the care provided by family members and others. Therefore, it would not be appropriate to include a factor in the rate that assumes the absence of these individuals.

We note, however, that on the basis of additional analysis of data from the HCFA demonstration project we have been able to identify a specific cost component associated with home respite and incorporate it into the routine home care rate. This is discussed more fully in the section concerning the components of each individual rate.

Comment: Some commenters suggested that HCFA develop exceptions to the proposed categories of rates when specific palliative procedures, such as radiation and chemotherapy, are provided on an inpatient or outpatient basis to hospice patients.

Response: We do not believe it desirable to fragment the rate structure in this manner. Fragmentation of the

rates may provide incentives for hospices to increase the use of "special procedures". The method by which we have chosen to reimburse hospice for physician services does enable the hospices to recover the costs of these services when they are provided by physicians. We also note that further analysis of HCFA data has enabled us to identify a cost component associated with outpatient hospital services (e.g., radiation or chemotherapy). We have added a cost component to the routine home care rate for those services that are provided to hospice patients but were not included in the hospice demonstration project's cost reports. We believe we have accounted for substantially all services received by demonstration hospice patients, whether or not furnished by the hospice. In addition, we believe that services required to be provided by hospices under the Medicare program were provided by the demonstration hospices or are otherwise accounted for in the reimbursement rates.

Comment: One commenter suggested the addition of a sub-acute inpatient level of care and stated it would permit hospices to provide inpatient care in other than hospital settings.

Response: We would point out that the general inpatient care rate is currently applicable to covered patient care furnished in freestanding hospice inpatient units as well as inpatient units in hospitals and skilled nursing facilities meeting additional staffing standards.

Comment: One commenter stated that the rate categories were ill-defined but offered no suggestions for improvement and stated that the categories were not based on the statute. Another commenter stated that more categories should be used, but did not elaborate.

Response: In the absence of further elaboration and suggestions, we believe the categories are sufficiently clear and distinct and adequately encompass the type of hospice care described in the statute.

(a) *Routine Home Care Payment.*

Comment: In the proposed regulations, a routine home care rate was to be paid for each day in which a Medicare patient was at home and not receiving continuous care. Specific comment was sought on the issue of whether it would be more desirable to use a per visit payment procedure (under which payment would be made only when services are provided) or the proposed per diem approach. We received eight comments advocating the per visit approach because commenters felt that the per diem approach was more prone to fraud and abuse, the per visit system would enable payment to be more closely tailored to patient care needs and would permit payment for multiple visits in the same day. Moreover, several of these commenters seemed satisfied with the per-visit approach because it is consistent with current home health agency reimbursement policies.

The five commenters supporting the per diem approach all stated that this mechanism was more consistent with the hospice concept of care.

Response: We have decided to adopt the per diem approach, as specified in the proposed rule. This decision is based on our belief that the per visit system introduces an incentive to provide additional services and is more complex than the per diem approach. We also intend to monitor the frequency of home services furnished to hospice patients to detect instances in which patients might be underserved. Substandard services would be a ground for exclusion from participation in the Medicare program.

(b) *Continuous Home Care Rate.*

Comment: We received 13 comments regarding the payment rate for continuous home care. In the NPRM, 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. Thus, we proposed a specific payment amount (the mean within each interval) for each of the following intervals of care: 8 to 16 hours, 16 to 20 hours, and 20 to 24 hours. The majority of these commenters objected to the fact that a hospice can never receive the full rate for care delivered for 24-hour period. These commenters all urged HCFA to pay the full rate for 24 hours of care.

Additionally, one commenter suggested that the 8–16 hour interval be divided into two 4-hour intervals.

Response: We agree that, after the threshold for recognition of continuous home care has been met, payment to the hospice should relate more directly to the number of hours of care actually provided. We are changing the regulations to establish an hourly rate for continuous care. We will retain the proposed requirement that in order to be paid at the continuous home care rate, a minimum of 8 hours of care must be provided. Therefore, the minimum rate for continuous home care will be the 8-hour threshold multiplied by the hourly rate. For each additional hour or portion of an hour, the hospice will be paid on the basis of the hourly rate.

(c) *Inpatient Respite Rate.*

Comment: Several commenters took issue with HCFA's use of SNF costs as the base for the inpatient respite rate. Most of these commenters stated that SNF or ICF beds were not available in their communities and that the rate would not cover care furnished in hospitals. A few commenters suggested that HCFA develop a separate inpatient respite rate when this type of care is furnished in hospitals.

Response: We believe that it is appropriate to base the respite rate on SNF costs. In our view, respite care does not necessitate an acute hospital level of care, and it would be inappropriate to encourage provision of this care in acute hospitals. We believe the respite care rate should reflect the level of care needed, and not the site in which it is provided.

(d) *General Inpatient Rate.*

Comment: Only a few comments were received regarding the payment procedures for general inpatient care. One comment suggested that we permit a specific rate for inpatient care for non-hospital based hospices since it was felt that arranging for hospital care would be more costly than inpatient care furnished in hospital-based hospices.

Response: We believe that it is most appropriate to base the general inpatient care rate on the cost experience of hospital-based hospices because those data actually reflect the unique cost experience of hospice inpatients. This is true because actual cost data were not collected under the demonstration project for inpatient care provided to patients of home health based hospices. Rather, costs were imputed for this care on the basis of the cost of care experienced under Medicare for its patient population in general. On the other hand, actual costs were collected from the hospital-based hospices. We believe that these cost data that reflect a unique pattern of ancillary services that can be directly associated with hospice care, are the most appropriate measure of the cost of hospice inpatient care.

Nevertheless, we recognize that hospices which are not hospital-based may have some difficulty arranging for inpatient services at a rate equal to the hospital's cost for those services. As discussed below, based on new data, we now calculate the cost of inpatient services to be less than that included in the proposal. It is impossible to compute what, if any, premium over these costs might be exacted by hospitals furnishing inpatient services to unassociated hospices. This would probably depend on local conditions. To allow for further review of this question, we are retaining the inpatient rate at the level proposed, which, in light of the new data and the few comments addressing the issue, appears to be adequate even for hospices that are not hospital-based.

3. *Determination of rates.*

(a) *Routine Home Care Rate.*

Comment: The majority of those commenting on the routine home care rate took issue with our decision not to apply an adjustment for the effects of inflation, because the data base was from 1981 demonstration costs.

Response: We agree with these commenters and have increased the home care rates to reflect inflation between 1982 and 1984 as measured by Medicare's home health care market basket index for that period.

Comment: A few commenters took issue with specific cost components of the routine home care rate, particularly drugs, supplies and equipment. These commenters expressed the view that the amounts allocated for these components were inadequate.

Response: We have carefully reviewed the demonstration data available at present and have concluded that these amounts are the best estimates available of the cost incurred and have adopted them for the final regulations. We note that the effect of the general inflation update has been to increase the amount allowed for these items.

Comment: One commenter stated that the drug cost component was artificially low since demonstration patients may have billed prescription charges outside the demonstration (e.g., to other third party payors, Medicaid or may have paid for drugs out of their own resources).

Response: We have used the drug cost data from the HCFA demonstration project in calculating rates for these final regulations because we have been unable to verify that the practice described by the commenters occurred.

(b) *Continuous Home Care Rate.*

Comment: We received two specific comments on the calculation of the continuous home care rate that claimed the calculation was inadequate because the rate was based on demonstration data that reflected the costs for a variety of disciplines, while the proposed regulation requires that the preponderance of care be nursing.

Response: We do not believe the methodology is flawed because there is no requirement that care be exclusively nursing care, nor are the services of a registered nurse required. Consequently, the comments were not accepted.

(c) *Inpatient Respite Rate Determination.*

Comment: Two commenters suggested that we include a component for the administrative and general cost of the hospice in our calculation of the rate because of the need for the hospice to coordinate and arrange for such care.

Response: We believe this cost has been incorporated in the component for the daily cost of the interdisciplinary team. Since inpatient respite care was provided to less than 1 percent of the patients during the hospice demonstration, our data do not permit us to further estimate the amount of this cost component at present.

(d) *General Inpatient Rates.*

Comment: Two commenters took issue with the base used in the calculation of the rate (1981 hospital based hospice operating cost $221). Both of these commenters suggested that the correct figure was $335.

Response: We believe that this comment, which is not accurate, resulted from a misunderstanding of the preliminary results of the hospice demonstration project. The correct figure was as described in the calculation, and the same methodology has been used in deriving the routine operating cost component in these final regulations.

Comment: Several commenters objected to the adjustment made in the calculation that reduced the incurred per diem routine cost by 29 percent, to reflect the relationship of the cost of the hospitals which were used in the demonstration to Medicare average routine cost. These commenters expressed the view that the per diem routine costs for hospice inpatients would not necessarily be the same as routine costs for non-hospice patients and therefore, the adjustment was questionable.

Response: The purpose of the adjustment was to reflect the fact that the routine costs of hospitals in the demonstration were 29 percent higher than the average Medicare hospital. The nature of routine costs is such that they do not vary significantly from one patient group to another. The incurred cost in the demonstration for the routine care component is, therefore, a reflection of the hospitals used by the demonstration hospices. Because we would not expect hospices to use this same distribution of hospitals after the benefit is implemented, the adjustment to the Medicare average cost is appropriate. We note that the use of ancillary services which may be expected to vary by type of patient, has been adjusted to reflect the experiences of the demonstration project.

4. *Limitation on inpatient care.*

Comment: Numerous commenters suggested that we delete the proposed limitation on inpatient care days described in § 418.302(f) of the proposed regulations. That limitation was to be applied to payment for inpatient care days in excess of the percent specified in the statute. The statute (section 1861(dd)(2)(A)(iii) of the Act) specifies that a hospice must assure that it does not exceed 20 percent of the aggregate number of days of hospice care provided to Medicare beneficiaries during any 12 month period.

Response: We are not accepting these comments and are retaining this limit because we believe a hospice should not be rewarded through the reimbursement system for exceeding the statutory limit. By making the 20 percent limit a reimbursement limit, the regulations provide an incentive for hospices to remain in compliance with the statutory requirement. We do not believe that costs attributable to excessive inpatient days are necessary in the efficient delivery of hospice services.

We are, however, making a change in how the limit is applied in order that the hospice may receive payment at the routine home care rate for those days in excess of the 20 percent limit, rather than being denied payment entirely, as was the case in the proposed rule. Interim payments made to the hospice for inpatient care will be compared to the new limit as follows:

(a) The maximum allowable number of inpatient days (this includes both general inpatient and inpatient respite) will be calculated by multiplying the total number of days of Medicare hospice care by 0.2.

(b) 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.

(c) If the total number of days of inpatient care exceeded the maximum allowable number, the limitation will be determined by:

(1) 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 that was made.

(2) Multiplying excess inpatient care days by the routine home care rate.

(3) Adding together the amounts calculated in (1) and (2) above.

(4) Comparing the amount in (3) above with interim payments made to the hospice for inpatient care during the "cap period".

Any excess reimbursement must be refunded by the hospice.

5. *Hospice cap.*

Comment: Several commenters took issue with § 418.309 of the proposed regulations which described the hospice cap. These comments dealt with specific services that are subject to the cap, indexing of the cap for regional variations, and exceptions to the cap.

Response: Pub. L. 98-90 modified the cap formula set forth in section 1814(i) of the Act. The revised cap amount is $6,500 for the first year of the benefit, inflated annually by the percentage change in the medical care component of the Consumer Price Index for All Urban Consumers (CPI). The revised cap is not subject to indexing for regional variations, as was the case under prior law.

We would also point out that all reimbursement to a hospice for hospice services, as defined in section 1861(dd)(1) of the Act, is subject to the cap. There is no authority to exempt physicians' services or other hospice services from the limitation. We believe it is clear from the legislative history that the cap is intended to capture all costs associated with hospice care. For example, the committee report (H. Rep. No. 98-333, 98th Cong., 1st Sess., 1, (1983)) that accompanied the amendment that raised the cap to $6,500 stated explicitly that the "* * * intent of the cap was to ensure that payments for hospice care would not exceed what would have been expended by Medicare if the patient had been treated in a conventional setting". Exempting some services from the cap would circumvent this intention. Finally, we believe that comments suggesting that the costs of individual patients who require costly or long-term hospice care be exempt from the cap result from a misperception of the statute's requirement. The cap is an aggregate limitation, not a limit on payment for any one individual.

6. *Update of rates.*

Comment: Six commenters suggested that HCFA adopt a specific mechanism for updating the payment rates on an annual basis. These commenters expressed the view that HCFA's plan to accumulate data from participating hospices for rate revision would result in hospice rates not being increased for too lengthy a period.

Response: We have not accepted this comment. In our view, the use of a fixed index is not an appropriate method to update rates. We intend to provide for the data accumulation and update, when warranted, as expeditiously as possible.

7. *Cost reports.*

Comment: Three commenters suggested that HCFA collect cost data from all hospices.

Response: We are accepting this comment because we believe it is important to have as complete a data base as possible for updating the payment rates and for use as a basis for evaluation of the hospice benefit in general.

8. *Other.*

Comment: Several commenters suggested that we adopt a common audit and reporting procedure for hospices which are part of another Medicare provider.

Response: In practice this will occur since both the hospice and the related provider will usually deal with the same intermediary. The intermediary will be responsible for assuring that costs are allocated correctly from the parent provider and that services are billed correctly.

Comment: Other commenters suggested that we use a periodic interim payment procedure, in which the intermediary would calculate a fixed monthly payment, and adjust for actual utilization.

Response: We believe the use of a prospective payment system will enable us to make timely and accurate payments without the use of a periodic interim payment system.

J. Copayments

Comment: Eight commenters suggested inclusion of a provision for repayment of bad debts, as is done for other Medicare providers.

Response: We are not including this provision for two reasons. First, we believe that the amount of unpaid Medicare copayments on outpatient drugs and inpatient respite care are apt to be negligible. The copayment on outpatient drugs is the lesser of 5 percent of the cost of the drug, or $5.00 per prescription. The copayment on inpatient respite care, which was furnished infrequently during the hospice demonstration, is $3.24 per day. We expect that the amount of uncollected copayments would be fairly limited, and it would not be cost effective to establish a separate administration mechanism for tracking and payment of specific noncollections. Secondly, since no deductibles or copayments were imposed on Medicare patients during the demonstration, we are not able to calculate an amount by which to adjust the prospective rates for estimated noncollection.

Comment: One commenter suggested the copayment requirement be eliminated, because of the financial hardship it might impose on beneficiaries.

Response: The copayments are statutory requirements specified in section 1813(a)(4) of the Act and there is no authority to eliminate them.

K. Appeals

Comment: A few commenters objected to the provisions in the proposed regulations regarding appeal procedures. Two commenters suggested the threshold amount for an intermediary hearing be reduced from a minimum of $1,000 in controversy to $100.

Response: We did not accept these comments, because a reduction would increase the number (and administrative expense) of these hearings and the current figure has worked well for other providers, such as home health agencies.

Comment: Several commenters urged that appeal procedures be described more completely.

Response: We agree that more detailed procedures would be helpful. As in the case of other provider appeals, we will provide a more detailed description in program manuals and instructions.

L. Designation of Intermediaries

Comments: A number of comments were received about the designation of intermediaries to serve hospices. Some commenters suggested that hospices should have the option of being served by HCFA's Office of Direct Reimbursement. Other comments suggested greater hospice choice of intermediaries. One commenter suggested that HCFA designate a smaller number of hospice intermediaries so that they could concentrate resources on hospice claims.

Response: We have adopted the suggestion of the commenter who proposed a smaller number of hospice intermediaries. This is in accordance with the statute that expressly authorizes the Secretary to assign hospices to intermediaries, although it requires due consideration be given to hospices whose parent organizations use a different intermediary. After reevaluating our proposal to designate one intermediary per State to serve freestanding hospices, we have decided to use only two intermediaries because of the relatively few freestanding hospices. We are retaining the provision that a hospice that is a part of another organization or agency already participating in Medicare will be serviced by the same intermediary that services the parent organization. We have continued to exclude the possibility of either a freestanding or provider-based hospice being served by the Office of Direct Reimbursement because, as we noted in the NPRM, we have proposed to reduce the number of providers dealing directly with HCFA.

The two designated intermediaries are Blue Cross of California and the Prudential Insurance Company of America. Blue Cross of California will serve freestanding hospices in those

States West of the Mississippi River and the Prudential Insurance Company will serve freestanding hospices in those States East of the Mississippi River. The entire States of Minnesota and Louisiana will be served by Blue Cross of California. It is HCFA's intent that all hospices receive the same level and quality of intermediary services. Based on the past performance of the designated hospice intermediaries, we believe they will have no problem handling their respective geographic areas and will provide a high level of service to hospices. However, if a freestanding hospice believes it would receive more efficient service from the hospice intermediary other than the one serving its area, the hospice may submit to HCFA under the change of intermediary regulations at 42 CFR 421.106, a request for a change of intermediary from its servicing intermediary to the other designated hospice intermediary. HCFA will consider the request. If HCFA determines that the requested change is in the best interest of the Government, the hospice's request for a change of intermediary will be approved. With respect to provider-based hospices, the change of intermediary regulations, 42 CFR 421.106, are applicable only to the parent providers of hospices.

Our strategy of designating two intermediaries to serve hospices is consistent with HCFA's policy of using an intermediary configuration which is in the best interest of effective and efficient administration of the Medicare program. With respect to the number of hospices, the Joint Commission for Accreditation of Hospitals (JCAH) report of March 1983 estimated the total number of hospices to be 1145, with no more than 471 freestanding. The JCAH further estimated no more than one-half of the 471 freestanding will participate in the Medicare program. Of the provider-based hospices, 437 are hospital-based, 219 are based in home health agencies and 18 are based in long term care facilities. Since a relatively small number of freestanding hospices are expected to participate in the Medicare program, it is reasonable to expect a low volume workload from these facilities. The two intermediaries will develop expertise in the processing of hospice claims that will lead to more uniformity of payment throughout the country. However, if in the future HCFA determines that the volume of workload generated by freestanding hospices, or other considerations, warrant the use of additional intermediaries, HCFA will designate the additional intermediaries to service freestanding hospices.

IV. Final Regulations

We are adopting the provisions set forth in the NPRM with the exceptions noted in the **"Discussion of Comments"** (section III. above) as well as the following changes.

A. Technical Changes

In the NPRM, we proposed technical changes to 42 CFR 405.310, 405.330 and 405.332. We are revising the changes that we had proposed to make them easier to read. We are making additional technical changes throughout these regulations to correct drafting errors, to clarify certain sections and to reflect changes in regulations that have occurred since the NPRM was published.

B. Payment Rates

In the NPRM we proposed that hospices would be paid one of four predetermined rates for each day in which a qualified Medicare beneficiary is under the care of the hospice. In calculating those payment rates, we used data obtained from the Medicare hospice demonstration project. We also pointed out that the data we used had not been finalized due to at least two factors. First, since patient-based data are not entered into the data files until three months after the patient has died, the data did not reflect the experience of all patients who received hospice care during the course of the demonstration. Secondly, the cost data used in the proposed rates were calculated from the 1981 cost reports of the 26 demonstration hospices. These reports were in the process of being audited and therefore, the reported costs could change somewhat.

A summary of the payment rates proposed in the NPRM follows:

1. Routine Home Care (per day)	$53.17
2. Continuous Home Care:	
Total continuous care rate	311.96
8 up to 16 hour interval	155.98
16 up to 20 hour interval	233.97
20 through 24 hour interval	285.96
3. Inpatient Respite Care (per day)	61.65
4. General Inpatient Care (per day)	271.00

The payment rates proposed in the NPRM were based on demonstration hospices' 1981 cost reports and the experience of Medicare patients in the hospice demonstration for whom data were available at the time the proposed rates were calculated. We now have data available from the demonstration hospices' 1982 cost reports and data on 3889 patients who entered the demonstration since October 1, 1980 (the inception of the project) and who died by April 1, 1983. We have used these later data in recalculating the home care payment rates. We have also incorporated in the methodology used for calculating these rates several refinements that were either suggested by commenters or that were made possible by the newer data.

The new hospice payment rates are calculated as follows:

1. *Routine home care rate.*

The following changes were made to the routine home care rate:

a. Average cost per visit figures for nursing, home health, and social service/therapy visits were recalculated based on 1982 cost data from the demonstration. Average visits per day for each of these three components were also recalculated based on the larger patient sample, but limited to include only utilization that occurred within the first 210 days of patient stays. This adjustment was necessary because there was no limit on the number of benefit days under the hospice demonstration.

b. We have added a cost component to the rate representing the cost of respite care delivered in the home. In the proposed regulation, we did not provide for a separate home respite care rate because the cost of a day of home respite care closely approximates the cost of routine home care. Since then, however, we have analyzed the costs associated with home respite care and developed a factor for inclusion in the routine home care rate that explicitly compensates the hospice for this care. This amount was calculated by dividing the home respite cost per patient by the average number of routine home care days in a typical hospice stay.

c. We have recalculated hospice interdisciplinary group costs based on 1982 demonstration data and have allocated this cost over the entire 70 day length of stay.

d. The 1982 data on the per diem cost of drugs, supplies and equipment is not available. Therefore, we have used the cost figures based on the earlier patient sample after updating for inflation to 1982.

e. As a result of comments, we have increased the routine home care rate for inflation from 1982 to 1984. To adjust for inflation, we have used a market basket index developed from the price of goods and services purchased by home health agencies. This is the same market basket index developed for use in connection with Medicare limits on home health costs.

f. A cost component was added representing hospital outpatient charges for services such as palliative radiation and chemotherapy. Under the hospice legislation these services will have to be

provided through the hospice. We have estimated the average daily cost of these services based on a sample of Medicare patients who died from cancer in 1980 inflated to 1984.

The revised calculation of the routine home care rate is as follows:

Service component	Average cost per visit	Average visits per day	Cost per day
Nursing	65.30	.223	14.56
Home Health	42.79	.267	11.42
Soc. Ser./Therapy	64.14	.045	2.89
Home respite			1.31
Interdisciplinary group			2.49
Drugs			1.06
Supplies			4.02
Equipment			1.01
Outpatient hospital therapies (1982 dollars)			2.68
Subtotal			41.44
Home health market basket 1982 to 1984			× 1.116
Routine Home Care Rate			46.25

2. *Continuous home care rate.*

We have revised the procedures for payment of the continuous home care rate as described in section III. I.2.b. Additionally we have recalculated the rate based on the newer demonstration data. The following changes in the calculation were made:

a. The cost and utilization components of nursing and therapy were updated based on 1982 demonstration data.

b. The cost per day for drugs, supplies, and equipment was updated for inflation to 1982.

c. Interdisciplinary group costs per patient were recalculated based on 1982 cost data and allocated across the 70 day average length of stay to yield an updated average cost per day.

d. The continuous home care rate was increased for the effects of inflation by using the Medicare market basket index developed for use in connection with the Medicare limits on home health costs. It measures the increases in the price of goods and services purchased by home health agencies.

The revised calculation is as follows:

Service component	Cost component	Utilization component	Cost per day
Nursing	$12.60 per hour	[1] 24	$302.40
Therapy	64.14 per visit	[2] .06	3.84
Drugs			2.23
Supplies			3.16
Equipment			7.27
Interdisciplinary group			2.49
Subtotal			321.39
Home health market basket 1982 to 1984			×1.116
Total Continuous Care Rate			358.67
Rate for 8 hours of Continuous Care			119.56
Hourly rate			14.94

[1] Hours.
[2] Visits per day.

3. *Inpatient respite rate.*

We made the following adjustments to the inpatient respite rate.

a. The 1982 per diem cost data for drugs, supplies, and equipment is not available. Therefore, the cost per day based on the earlier patient sample was used after updating for inflation to 1982.

b. Interdisciplinary group costs per patient were recalculated based on 1982 cost data and allocated across the 70 day average length of stay to yield an updated average cost per day.

c. The inflation factor we used is a market basket index that reflects the changes in the prices of goods and services purchased by skilled nursing facilities (SNFS) from 1982 to 1984.

The revised calculation is 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	8.58
Subtotal	53.43
SNF market basket 1982 to 1984	×1.09
Subtotal	58.24
Less 5 percent copayment	−2.91
Inpatient Respite Rate	55.33

4. *General inpatient rate.*

In the NPRM, we proposed to pay a hospice a general inpatient rate for inpatient care for pain control or acute or chronic symptom management. The proposed rate was $271, which was comprised of a $171 component for routine care, $45 for ancillary services and $55 for inflation since the data were based on 1981 demonstration costs.

We recalculated the rate using the 1982 cost data and adjusted the rate to include explicit recognition of daily interdisciplinary group costs. These changes would result in a general inpatient rate of $255, which is somewhat lower than that proposed. In light of the concern, discussed above, that non-hospital based hospices may have to arrange for inpatient care with hospitals at a higher rate than the cost actually incurred by the hospitals, we have decided to retain the proposed rate of $271.00 pending the acquisition of additional information with which to evaluate whether a different inpatient rate is appropriate. The rate was calculated as follows:

Hospital based hospice routine operating cost per day	171.00
Ancillary cost per day, from demonstration	45.00
Subtotal	216.00
Inflation to 1984	1.256
General Inpatient Care Rate	271.00

C. Local Adjustment of Payment Rates

In the NPRM, we proposed to use a mechanism for the local adjustment of the payment rates to reflect the differences from area to area in wage levels. Because hospice care is relatively labor intensive, this 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. The methodology used in calculating the dollar amount of each rate subject to the wage index remains unchanged. The following wage/nonwage proportions published in the NPRM will continue to be used.

Rate	Wage component (percent)	Non-wage component (percent)
Routine home care	68.71	31.29
Continous home care	68.71	31.29
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 ($214.78) only after updating for inflation.

In calculating the amount of each rate to be adjusted, we multiplied the national rate by the appropriate portion from the table above. In the case of the inpatient respite rate, the procedure was applied only to the SNF cost component after updating for inflation ($48.89). In the case of the general inpatient rate, the procedure was applied only to the routine cost component, after updating for inflation ($214.78). Again, this is consistent with the methodology used in the proposed rule. The following table shows 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	$46.25	$31.78	$14.47
Continuous home care	358.67	246.44	112.23
Inpatient respite	55.33	29.95	25.38
General inpatient	271.00	173.48	97.52

The wage indices that apply to the hospice benefit are the same as those for the Medicare prospective payment regulations for inpatient hospital services published in the **Federal Register** on September 1, 1983 (48 FR 39871–39875), Tables 4a. and 4b. In the NPRM, we had proposed a wage index that related 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. However, on June 30, 1983, the

Executive Office of Management and Budget (EOMB) began using Metropolitan Statistical Areas (MSAs) instead of SMSAs. Therefore, the indices published in the cited tables reflect this redesignation of metropolitan areas, and relate the wage levels in each MSA and rural area within a State to a national norm of 1.0.

In applying the wage index to the hospice rates, we will not apply an index lower than 0.8. We are using this "floor" on the index to take account of those localities (rural areas in five states) that have current indices below this level. We recognize that hospices will need to attract and retain sufficient skilled staff to provide the hospice benefit, and we believe that use of an index below 0.8 will unduly jeopardize the availability of the benefit in these areas.

D. Hospice Cap

Section 1814(i) of the Act imposes an aggregate cap on Medicare payments to any hospice. The aggregate cap amount for any given hospice is established by multiplying a cap amount by the number of Medicare beneficiaries who received hospice services during the year. Based on the provisions of the statute prior to August 29, 1983, we included in the NPRM an estimate of $4,232 as the average cap amount per beneficiary for the first year of the hospice program. Since the NPRM was published, Congress has amended section 1814(i) of the Act regarding the cap amount to specify a cap amount of $6,500 per beneficiary. The statute provides, as will these final regulations, that the new cap amount be adjusted for increases or decreases in medical care expenditures. Section 1814(i)(2)(B) of the Act specifies that this adjustment must 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 Bureau of Labor Statistics (BLS), from March 1984 to the fifth month of the accounting year. The statute, as amended, does not provide for the regional adjustments to the cap that were included in the statutory language prior to August 29, 1983. Therefore, we have deleted provisions for regional adjustments that were included in the NPRM. The $6,500 cap is a national cap with no regional variations.

As specified in the NPRM, it is not necessary to make the cap calculation specific to each hospice's fiscal reporting year. Rather, since the program began on November 1, 1983, we will calculate the cap for each hospice for a period beginning on November 1 and ending October 31. (Since the appropriate CPI factor is not published by November of each year, hospices will not know the exact cap amount at the beginning of each reporting period.) The cap amount will be adjusted to account for changes in the cost of medical care caused by changes in the economy for March 1984 to the fifth month of the accounting year. The total payment made for services furnished during this period will be compared to the aggregate cap for this period.

In the NPRM, we used the length of stay data collected through the Medicare hospice demonstration project to determine the point at which to include a beneficiary in calculating the hospice cap amount. In the NPRM, the mean number of hospice benefit days equaled 44 days. Based on the more recent data available, the average length of hospice stay is now estimated at 70 days. Therefore, for purposes of calculating the hospice cap, the hospice should count beneficiaries who filed an initial election to receive hospice care after September 27, which is less than 35 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. Thus, the cap will be calculated by multiplying $6500 by 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 September 27 of the previous year through September 27 of the current year.

The statutory exception to the application of the aggregate cap amount for hospices that began operation before January 1, 1975 remains in these final regulations.

V. Home Visits

The hospice benefit is, in our judgment, materially different in many ways from other Medicare services. The vast majority of the services are performed in the patient's home, and the type of care specified in the benefit makes it critically important to assure that services are coordinated and delivered properly if quality of care is to be assured. As a result, we have determined that reviews of a hospice's records and surveys of its inpatient facilities are not adequate to permit a full assessment of hospice's compliance with the conditions of participation. We also believe that it is not feasible to base payment determinations solely on the basis of documents in the claims process. Instead, we plan to augment both the survey and certification process and the claims process by conducting visits to the homes of the patients to consult with them and with their families. The information elicited will vary with the purpose of the visit.

Visits by representatives of the State survey agency will be for the purpose of obtaining information concerning the conditions of participation. For example, they may wish to determine whether the patient received services consistent with the plan of care, whether volunteer visits took place and whether they were adequate, whether home health aide services were properly supervised, or whether the patient viewed the services as adequate. Visits will only be conducted with the consent of the patient and are not a condition of payment or coverage and may be declined if a patient does not wish to participate.

Visits by representatives of the fiscal intermediary will be conducted to assure that proper payment determinations are made on hospice claims. These visits will be conducted by medical review personnel of the fiscal intermediaries who will be interested in learning whether billed and provided services were covered and, if so, were provided in an amount adequate to meet the needs of the patients. Some visits will also be made to determine whether hospice revocations were voluntarily made. Patients will not be visited unless they have signed a consent statement (that will be made available to them upon admission to a hospice program) that fully explains their right to refuse a visit and advises them that refusal to consent to a visit will not affect payment on their behalf for hospice services. (Although a visit by intermediary medical review staff may result in adjustment of payment to a hospice, a beneficiary would be offered the protections of Medicare's waiver of liability provision.)

VI. Impact Analyses

Executive Order 12291 requires us to prepare and publish a regulatory impact analysis for any regulations that are likely to have an annual effect on the economy of $100 million or more, cause a major increase in costs or prices, or meet other threshold criteria that are specified in that order. In addition, the Regulatory Flexibility Act (Pub. L. 96-354) requires us to prepare and publish a regulatory flexibility analysis for regulations unless the Secretary certifies that the regulations will not have a significant economic impact on a substantial number of small entities. (For purposes of the Regulatory

Flexibility Act, small entities include all nonprofit and most for-profit hospitals.) Under both the Executive Order and the Regulatory Flexibility Act (RFA), such analyses must, when prepared, show that the agency issuing the regulations has examined alternatives that might minimize unnecessary burden or otherwise ensure the regulations to be cost-effective.

A. Changes from the NPRM

As stated above, we are adopting the provisions in the NPRM except as noted throughout this preamble. Most of these changes are merely technical clarifications generating no additional economic impact on the program, affected providers, or beneficiaries (e.g., the professional management provisions under § 418.56).

A few changes we have made to the NPRM provisions could result in some additional administrative costs or benefits to the program, to hospices or to beneficiaries.

1. *Negligible cost impact.*

A provision that could produce a negligible cost impact is the provision relating to cost reporting. In response to several comments, we have decided to require that hospices submit cost reports to the Secretary. We anticipate some costs to the provider to complete and settle their reports. However, these cost reports will allow us to create a hospice data base from which we can evaluate the program and update the payment rates as necessary.

2. *Benefits.*

Several of the changes from the NPRM will also result in benefits, both quantitative and qualitative, to the program, to hospices and to beneficiaries. Included among these provisions are:

• *Short term inpatient care*—By requiring that general inpatient care be provided in a hospital, an SNF or a freestanding hospice that meets the strengthened conditions, we believe that beneficiaries will receive more comprehensive and higher quality care than an ICF setting. The program benefits by providing better care at the same payment rate, thus, incurring no additional costs in providing an increased level of care.

• *Required services*—In the preamble, we enumerated the basic services that a hospice must routinely make available on a 24-hour a day basis. We believe that clearly delineating critical from noncritical services will allow hospices to determine their own service mix and accompanying staffing arrangements to meet the specific needs of their patients. This flexibility should allow for more cost-effective provision of care to hospice patients.

• *Election statement*—By permitting a representative of the individual to sign the election form, we want to assure access to hospice services for all beneficiaries who need this care. In making this change, we hope to avoid unnecessary burdens for the family and the patient in receiving care when the patient is incapable of signing the election statement.

• *Medical supplies*—In response to several comments, we are changing the condition of participation governing medical supplies and drugs to allow family members to administer drugs to patients in accordance with applicable State and local laws. This change supports our objective of enabling the terminally ill patient to remain at home under the care of family members as long as possible. We believe that this change will further involve the family with the care and treatment of their family members.

3. *Hospice cap.*

Another change from the NPRM is the increase in the hospice cap from $4232 to $6500 as mandated by Congress. Congress has established a hospice "cap" on the maximum amount of reimbursement to each hospice program, which will be indexed by the medical care component of the Consumer Price Index (CPI).

We believe that this change in the cap amount will not influence our estimates of the effects of these provisions for two reasons. First, the cap amount is not a factor in our estimation process but operates apart from the cost/savings impacts to constrain aggregate program payments. Second, our demonstration data indicates that the majority of hospice patients either die or are discharged before the hospice incurs patient care costs that approach the cap amount. Therefore, we believe this increase should not result in any additional program expenditures.

4. *Payment rates.*

We now have data available from the demonstration hospices' 1982 cost reports and data on those patients who entered the demonstration since October 1, 1980 (the inception of the project) and who died by April 1, 1983. We have used these later data in recalculating the home care payment rates. We have also incorporated several refinements in the methodology used for calculating the rates that were either suggested by commenters or that were made possible by the newer data.

The incorporation of the new data with the methodological refinements results in a change in the FY 1986 budget estimate. The FY 1984 and FY 1985 budget estimates, as noted in the NPRM, remain unchanged. Thus, the estimated budget impact of these final regulations are as follows:

Costs in millions

FY 1984	$60
FY 1985	110
FY 1986	170

5. *Fiscal intermediaries.*

As noted above, we are designating only two intermediaries to service freestanding hospices and the few hospices whose parent providers deal directly with our Office of Direct Reimbursement. We believe that this change from the NPRM will not result in any additional costs as we do not anticipate an incremental increase in claims processing volume due to this new intermediary configuration. The two designated intermediaries processing these claims should not realize a marked increase in their volume of claims as the workload from freestanding hospices is expected to be low. Also, based on the past performance of the designated hospice intermediaries, we believe that the intermediaries will handle their respective geographic areas and the anticipated number of freestanding hospices, and will continue to provide a high level of service to hospices.

However, we will designate additional intermediaries to service freestanding hospices if we determine that the workload volume, generated by these hospices, increases significantly.

Finally, in the event that a hospice believes it would receive more efficient services from the hospice intermediary other than the one servicing its area, it may request from HCFA a change of intermediaries. HCFA will consider the request and determine whether it is in the best interest of the Medicare program to allow the change.

B. Public Comments

We received two comments on the Impact Analysis published with the NPRM.

One commenter indicated that small, rural hospices will not be able to qualify for Medicare reimbursement because of the absence of a large population to draw from, and resources and available manpower to operate a facility that can meet our certification standards.

We believe that the law and these final regulations do not prohibit participation in the Medicare program by an organization that arranges for some services as long as it provides the core services directly. A hospice may arrange for noncore services with other

providers but may not participate in Medicare if it obtains the core services from another organization or agency. Thus, it is possible that because of the statutorily mandated core service requirement, some self-designated hospices (whether they are urban or rural) may not be able to participate because of the personnel costs associated with obtaining employees to furnish the core services. However, it is our view that this potential situation is the result of the statute and not these regulations that implement the statute.

A second commenter challenged some of the actuarial assumptions used in the cost estimating model. Based on the program experience of this one hospice, their patients experienced longer lengths of stay in hospitals or SNFs, after cancer was initially diagnosed, than the average length of stay experienced by hospice patients in our demonstrations. The commenter concluded that as a result of this experience, the Medicare program should realize increasing savings, not costs, from the hospice program.

We have not accepted this comment for two reasons. First, it should be noted that savings for the hospice program cannot be calculated on the basis of the average length of stay. The actual distribution of hospice length of stay and of hospital utilization by length of time prior to death must be used to capture the relationship between hospice cost and hospital savings but cannot be used in the estimating process. Second, we believe that the commenter erred in extrapolating their program's experience and limited date base to the entire Medicare program. The data underlying the actuarial cost estimates was used on 3 consecutive years of Medicare history file data and about 1,000 hospice patients participating in our demonstration projects. We believe that this large, more comprehensive data base provides a better means of estimating the effects of these provisions.

Summary

As discussed in the preamble of the NPRM and this analysis, the major economic impact of the hospice program is caused by statutory provisions and not this rule. We have, therefore, determined that this is not a major rule under Executive Order 12291. Further, as required by section 2 of the Executive Order, we believe that these final regulations maximize net benefits to society and result in the least net cost to all affected parties. We have also sought to achieve the objectives of the statute without imposing unnecessary burdens on hospices and beneficiaries.

Therefore, we have determined, and the Secretary certifies under 5 U.S.C. 605(b) of Pub. L 96-354 (The Regulatory Flexibility Act of 1980), that these final rules will not result in an economic impact of $100 million or have significant impact on a substantial number of small entities.

VII. Information Collection Requirements

Sections 418.22, 418.26, 418.56, 418.58, 418.70, 418.74, and 418.100 of this regulation, which involve reporting or recordkeeping requirements, were approved by Executive Office of Management and Budget (EOMB) on October 20, 1983 in accordance with the Paperwork Reduction Act of 1980. The EOMB approval number is OMB. No. 9038-0302.

VIII. Waiver of Delayed Effective Date

As specified in section 122(h)(1)(A) of TEFRA, the statutory amendments establishing the Medicare hospice benefit "* * * apply to hospice care provided on or after November 1, 1983, and before October 1, 1986." We cannot implement that statute until final regulations are in place. Because these regulations implement a new benefit and because they have been revised consistent with public comment, we believe that the public interest is best served by making these regulations effective without the usual 30-day delay. Accordingly, we find "good cause" for waiving the delayed effective date.

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, 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

Abuse, Administrative practice and procedure, Contracts (Agreements), Conviction, Convicted, Courts, Exclusion, Fraud, Health care, Health facilities, Health maintenance organizations (HMO), Health professions, Health suppliers, , Information (Disclosure), Lawyers, Medicaid, Medicare, Penalties, Professional Standards Review Organizations (PSRO), Reporting requirements, Supervision.

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, Health care, Health facilities, Medicare, Provider agreements, Rural health clinics, Termination procedures.

42 CFR Chapter IV is amended 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

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SUBCHAPTER B—MEDICARE PROGRAMS

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Part 418—Hospice Care

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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, 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, 1815, 1833, 1842, 1861, 1862, 1866, 1870, 1871, and 1879 of the Social Security Act (42 U.S.C. 1302, 1395g, 1395l, 1395u, 1395x, 1395y, 1395cc, 1395gg, 1395hh, 1395pp), and 31 U.S.C. 3711.

2. The table of contents for Subpart C is amended by revising §§ 405.310 and 405.330 to read as follows:

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

* * * * *

405.310 Particular services excluded from coverage.

* * * * *

405.330 Payment for certain excluded services.

* * * * *

3. Section 405.310 is amended by revising the title, the introductory paragraph and paragraphs (g), (j) and (k) to read as follows:

§ 405.310 Particular services excluded from coverage.

The following services are excluded from coverage:

* * * * *

(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, except as necessary for the palliation or management of terminal illness as provided in Part 418 of this chapter. The use of a television set or a telephone are examples of personal comfort services.

(k) Any items and services that are not reasonable and necessary for one of the following purposes:

(1) For the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member.

(2) In the case of hospice services, for the palliation or management of terminal illness, as provided in Part 418 of this chapter.

* * * * *

3. Section 405.330 is amended by revising the title and paragraph (a) to read as follows:

§ 405.330 Payment for certain excluded services.

(a) Notwithstanding the exclusions set forth in § 405.310, payment may be made for services that involve custodial care (as specified in § 405.310(g)), or are not "reasonable and necessary" (as specified in § 405.310(k)), if—

(1) The items and services were furnished by a provider or supplier under assignment; and

(2) Neither the individual to whom the items and services were furnished, nor the provider or supplier who furnished the services knew, or could reasonably have been expected to know, that the items or services were excluded from coverage in accordance with § 405.310(g) or § 405.310(k).

* * * * *

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 furnished.* 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" or as "not reasonable and necessary" as set forth in § 405.310 (g) and (k), respectively. 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, 1833(a), 1861(v), 1871, 1881, 1886, and 1887 of the Social Security Act as amended (42 U.S.C. 1302, 1395f(b), 1395g, 1395l(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, are 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 is based on the reasonable cost of services.) Public providers of service furnishing services free of charge or at a nominal charge are 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. This principle does not apply to payments for the costs of Part A inpatient hospital services for cost reporting periods subject to the rate of increase ceiling under § 405.463 or the prospective payment system under § 405.471. However, the carryover from previous periods is recognized, subject to the provisions of paragraph (d) of this section. For special rules concerning HMO's and providers of services and other health facilities that are owned or operated by an HMO, or related to an HMO by common ownership 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 of the 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 418, 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

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—Inservice 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 Services

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.
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 for physician services.
418.306 Determination of payment rates.
418.308 Limitation on the amount of hospice payments.
418.309 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 of the Social Security Act (42 U.S.C. 1395c–1395f, 1395x–1395cc and 1395hh).

Subpart A—General Provision 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 Medicare's supplementary medical insurance program.

"Election period" means one of three periods for which an 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 appropriately trained and assigned to 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.

"Representative" means a person who is, because of the individual's mental or physical incapacity, authorized in accordance with State law to execute or revoke an election for hospice care or terminate medical care on behalf of the terminally ill individual.

"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 after 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 then 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 care elects to receive that care, he or she must file an election statement with a particular hospice. An election may also be filed by a representative as defined in § 418.3. 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 or representative may designate an effective date for the election period that begins with the first day of hospice care or any subsequent day of hospice care.

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

(e) *Waiver of other benefits.* An individual waives 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) The individual's or representative's acknowledgement that he or she has been given a full understanding of the palliative rather than curative nature of hospice care, as it relates to the individual's terminal illness.

(c) Acknowledgement that certain Medicare services are waived by the election.

(d) The effective date of the election.

(e) The signature of the individual or representative.

§ 418.28 Revoking the election of hospice care.

(a) An individual or representative may revoke the individual's election of hospice care at any time during an election period.

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

(1) A signed statement that the individual or representative revokes the individual's 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 or representative may not designate an effective date earlier than the date that the revocation is made).

(c) An individual, upon revocation of 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 or representative may change, once in each election period, the designation of the particular hospice from which hospice care will be received.

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

(c) To change the designation of hospice programs, the individual or representative must file, with the hospice from which care has been received 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 paragraph (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 nursing services, physician services, and drugs and biologicals routinely available on a 24-hour basis;

(2) Make all other covered services available on a 24-hour basis 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; and

(3) Provide these services in a manner consistent with accepted standards of practice.

(c) *Standard: Disclosure of information.* The hospice must meet the disclosure of information requirements at § 420.206 of this chapter.

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 designate an individual who is responsible for the day to day management of the hospice program.

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 hospice employee who is a doctor of medicine or osteopathy who assumes overall responsibility for the medical component of 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.

(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 delineation of the role(s) of the hospice and the contractor in the admission process, patient/family assessment, and the interdisciplinary group care conferences.

(5) Requirements for documenting that services are furnished in accordance with the agreement.

(6) The qualifications of the personnel providing the services.

(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 persons meeting the qualifications of this part, and in accordance with the patient's plan of care and the other 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 in a legally binding written agreement that meets the requirements of paragraph (b) and that also specifies, at a minimum—

(1) That the hospice furnishes to the inpatient provider a copy of the patient's plan of care and specifies the inpatient services to be furnished;

(2) 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;

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

(4) The party responsible for the implementation of the provisions of the agreement; and

(5) That the hospice retains responsibility for appropriate hospice care training 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 or physician designee 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 or physician designee 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 a Medicare beneficiary because of the beneficiary'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 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 has been obtained for every individual, either from the individual or representative as defined in § 418.3.

§ 418.64 Condition of participation—Inservice training.

A hospice must provide an ongoing program for the training 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, home care and care provided under arrangements. The findings are used by the hospice to correct identified problems and to revise hospice policies if necessary. Those responsible for the quality assurance program must—

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

(b) Identify and resolve problems; and

(c) Make suggestions for improving patient care.

§ 418.68 Condition of participation—Interdisciplinary group.

The hospice must designate an interdisciplinary group or groups composed of individuals who provide or supervise the care and services offered by the hospice.

(a) *Standard: Composition of group.* The hospice must have an interdisciplinary group or groups that include at least the following individuals who are employees of the hospice:

(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) If a hospice has more than one interdisciplinary group, it must designate in advance the group it chooses to execute the functions described in paragraph (b)(4) of this section.

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

§ 418.70 Condition of participation—Volunteers.

The hospice in accordance with the numerical standards, specified in paragraph (e) of this section, uses volunteeers, in defined roles, under the supervision of a designated hospice employee.

(a) *Standard: Training.* The hospice must provide appropriate orientation and training that is consistent with acceptable standards of hospice practice.

(b) *Standard: Role.* Volunteers must be used in administrative or direct patient care roles.

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

(d) *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 are 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 (d)(1) for the amount of time specified in paragraph (d)(2).

(e) *Standard: Level of activity.* A hospice must document and maintain a volunteer staff sufficient to provide administrative or direct patient care in an amount that, at a minimum, equals 5 percent of the total patient care hours of all paid hospice employees and contract staff. 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.

(f) *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 request 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 Federal, State and local laws and regulations.

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

(b) *Standard: Licensure of employees.* Employees who provide services must

be licensed, certified or registered in accordance with applicable Federal or State laws.

§ 418.74 Condition of participation—Central clinical records.

In accordance with accepted principles 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 person 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.

In addition to palliation and management of terminal illness and related conditions, physician employees of the hospice, including the physician member(s) of the interdisciplinary group, must also meet the general medical needs of the patients to the extent that these needs are not met by the attending physician.

§ 418.88 Condition of participation—Counseling services.

Counseling services must be available to both the individual and the family. Counseling includes bereavement counseling, providing after the patient's death as well as dietary, spiritual and any other counseling services for the individual and family provided 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). A special coverage provision for bereavement counseling is specified § 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(f).

(d) *Standard: Additional counseling.* Counseling may be provided by other members of the interdisciplinary group as well as by other qualified professionals as determined by the hospice.

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 frequency 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.* A registered nurse must visit the home site at least every two weeks when aide services are being provided, and the visit must include an assessment of the aide services.

(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.

(a) *Standard: Administration.* All drugs and biologicals must be administered in accordance with accepted standards of practice.

(b) *Standard: Controlled drugs in the patient's home.* The hospice must have a policy for the disposal of controlled drugs maintained in the patient's home when those drugs are no longer needed by the patient.

(c) *Standard: Administration of drugs and biologicals.* Drugs and biologicals 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.

(4) Any other individual in accordance with applicable State and local laws. The persons and each drug and biological they are authorized to administer must be specified in the patient's plan of care.

§ 418.98 Condition of participation—Short term inpatient care.

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

Must be provided in a participating Medicare or Medicaid facility.

(a) *Standard: Inpatient care for symptom control.* Inpatient care for pain control and symptom management must be provided in one of the following:

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

(2) A hospital or an SNF that also meets the standards specified in § 418.100 (a) and (f) regarding 24-hour nursing service and patient areas.

(b) *Standard: Inpatient care for respite purposes.* Inpatient care for respite purposes must be provided by one of the following:

(1) A provider specified in paragraph (a) of this section.

(2) An ICF that also meets the standards specified in § 418.100 (a) and (f) regarding 24-hour nursing service and patient areas.

(c) *Standard: Inpatient care limitation.* Except as provided in paragraph (d) 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.

(d) *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 (c).

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 all of the following standards.

(a) *Standard: Twenty-four-hour nursing service.*

(1) The facility provides 24-hour nursing services which are sufficient to meet total nursing needs and which are in accordance with the patient plan of care. Each patient receives treatments, medications, and diet as prescribed, and is kept comfortable, clean, well-groomed, and protected from accident, injury, and infection.

(2) Each shift must include a registered nurse who provides direct patient care;

(b) *Standard: Disaster preparedness.* The hospice has an acceptable written plan, periodically rehearsed with staff, with procedures to be followed in the event of an internal or external disaster and for the care of casualties (patients and personnel) arising from such disasters.

(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).

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

(2) 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.

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

(g) *Standard: Patient rooms and toilet facilities.* Patient rooms are designed and equipped for adequate nursing care and the comfort and privacy of patients.

(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.* The hospice has available at all times a quantity of linen essential for proper care and comfort of patients. Linens are handled, stored, processed, and transported in such a manner as to prevent the spread of infection.

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

(k) *Standard: Meal service, menu planning, and supervision.* 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;

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

(3) 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; and

(4) If the hospice has patients who require medically prescribed special diets, have the menus for those patients planned by a professionally qualified dietitian and supervise the preparation and serving of meals to insure that the patient accepts the special diet.

(l) *Standard: Pharmaceutical hospice service.* The hospice provides appropriate methods and procedures for the dispensing and administering of drugs and biologicals. Whether drugs and biologicals are obtained from community or institutional pharmacists or stocked by the facility, the facility is responsible for drugs and biologicals for its patients, insofar as they are covered under the program and for ensuring that pharmaceutical services are provided in accordance with accepted professional principles and appropriate Federal, State, and local laws. (See § 405.1124(g), (h), and (i) of this chapter.)

(1) *Licensed pharmacist:* The hospice must—

(i) Employ a licensed pharmacist; or

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

(2) *Orders for medications.*

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

(ii) If the medication order is verbal—

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

(B) 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.

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

(i) A licensed nurse or physician.

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

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

(4) *Control and accountability.* The pharmaceutical service has procedures for control and accountability of all drugs and biologicals throughout the facility. Drugs are dispensed in compliance with Federal and State laws. Records of receipt and disposition of all controlled drugs are maintained in sufficient detail to enable an accurate reconciliation. The pharmacist determines that drug records are in order and that an account of all controlled drugs is maintained and reconciled.

(5) *Labeling of drugs and biologicals.* The labeling of drugs and biologicals is based on currently accepted professional principles, and includes the appropriate accessory and cautionary instructions, as well as the expiration date when applicable.

(6) *Storage.* In accordance with State and Federal laws, all drugs and biologicals are stored in locked compartments under proper temperature controls and only authorized personnel have access to the keys. Separately locked compartments are provided for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention & Control Act of 1970 and other drugs subject to abuse, except under single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected. An emergency medication kit approved by the pharmaceutical services committee is kept readily available.

(7) *Drug disposal.* Controlled drugs no longer needed by the patient are disposed of in compliance with State requirements. In the absence of State requirements, the pharmacist and a registered nurse dispose of the drugs and prepare a record of the disposal

Subpart D—Covered Services

§ 418.200 Requirements for coverage.

To be covered, hospice services must meet the following requirements. They 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. The 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 caregiver 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 or SNF, 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. Respite care must be furnished as specified in § 418.98(b). 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 a cap amount specified in § 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 care 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 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 hospice payment on a continuous care day varies depending on the number of hours of continuous services provided. The continuous home care rate is divided by 24 to yield an hourly rate. The number of hours of continuous care provided during a continuous home care day is then multiplied by the hourly rate to yield the continuous home care payment for that day. A minimum of 8 hours of care must be furnished on a particular day to qualify for the continuous home care 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) The 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 is determined in accordance with the procedures specified in paragraph (f)(5) of this section. That 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.

(5) If a hospice exceeds the number of inpatient care days described in paragraph (f)(4), the total payment for inpatient care is determined as follows:

(i) Calculate the ratio of the maximum number of allowable inpatient days to the actual number of inpatient care days furnished by the hospice to Medicare patients.

(ii) Multiply this ratio by the total reimbursement for inpatient care made by the intermediary.

(iii) Multiply the number of actual inpatient days in excess of the limitation by the routine home care rate.

(iv) Add the amounts calculated in paragraphs (f)(5) (ii) and (iii) of this section.

§ 418.304 Payment for physician services.

(a) The following services performed by hospice physicians are included in the rates described in § 418.302:

(1) General supervisory services of the medical director.

(2) Participation in the establishment of plans of care, supervision of care and services, periodic review and updating of plans of care, and establishment of governing policies by the physician member of the interdisciplinary group.

(b) For services not described in paragraph (a) of this section, a specified Medicare contractor 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 specified in § 418.309.

(b) Until October 1, 1966, payment to a hospice that began operation before January 1, 1975 is not limited by the amount of the hospice cap specified 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. Hospice cap amount.

The hospice cap amount is calculated using the following procedures:

(a) The cap amount is $6,500 per year and is adjusted for inflation or deflation for cap years that end after October 1, 1984, by using the percentage change in the medical care expenditure category of the Consumer Price Index (CPI) for urban consumers that is published by the Bureau of Labor Statistics. This adjustment is made using the change in the CPI from March 1984 to the fifth month of the cap year. The cap year runs from November 1 of each year until October 31 of the following year.

(b) Each hospice's cap amount is calculated by the intermediary by multiplying the adjusted cap amount determined in paragraph (a) 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 September 28 (35 days before the beginning of the cap period) and ending on September 27 (35 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 spent 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) if the amount in controversy is at least $1,000 or $10,000, respectively. 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. The methods and standards for the calculation of the payment rates by HCFA are not subject to appeal.

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, 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, 1874 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 may request a change of intermediary, or except for a hospice, 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 1816(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 Secretawry 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: Secs. 1102, 1814(a), 1861, 1864, 1866, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395f(a), 1395x, 1395aa, 1395cc, and 1395hh).

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: October 31, 1983.

Carolyne K. Davis,

Administrator, Health Care Financing Administration.

Approved: November 4, 1983.

Margaret M. Heckler,

Secretary.

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