

and revise paragraph (d) to read as follows:

§ 476.78 Responsibilities of health care providers.

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(b) *Cooperation with QIOs.* Health care providers that submit Medicare claims must cooperate in the assumption and conduct of QIO review. Providers must—

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(2) Provide patient care data and other pertinent data to the QIO at the time the QIO is collecting review information that is required for the QIO to make its determinations. The provider must photocopy and deliver to the QIO all required information within 30 days of a request. QIOs pay providers paid under the prospective payment system for the costs of photocopying records requested by the QIO in accordance with the payment rate determined under the methodology described in paragraph (c) of this section and for first class postage for mailing the records to the QIO. When the QIO does postadmission, preprocedure review, the facility must provide the necessary information before the procedure is performed, unless it must be performed on an emergency basis.

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(4) When the provider has issued a written determination in accordance with § 412.42(c)(3) of this chapter that a beneficiary no longer requires inpatient hospital care, it must submit a copy of its determination to the QIO within 3 working days.

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(c) *Photocopying reimbursement methodology for prospective payment system providers.* Providers subject to the prospective payment system are paid for the photocopying costs that are directly attributable to the providers' responsibility to the QIOs to provide photocopies of requested provider records. The payment is in addition to payment already provided for these costs under other provisions of the Social Security Act and is based on a fixed amount per page as determined by CMS as follows:

* * * * *

(4) CMS will periodically review the photocopy reimbursement rate to ensure that it still accurately reflects provider costs. CMS will publish any changes to the rate in a Federal Register notice.

(d) *Appeals.* Reimbursement for the costs of photocopying and mailing records for QIO review is an additional payment to providers under the prospective payment system, as specified in §§ 412.115, 413.355, and

484.265 of this chapter. Thus, appeals concerning these costs are subject to the review process specified in part 405, subpart R of this chapter.

PART 484—HOME HEALTH SERVICES

1. The authority citation for part 484 continues to read as follows:

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

2. Add a new § 484.265 to read as follows:

§ 484.265 Additional payment.

An additional payment is made to a home health agency in accordance with § 476.78 of this chapter for the costs of photocopying and mailing medical records requested by a QIO.

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

Dated: March 27, 2002.

Thomas A. Scully,

Administrator, Center for Medicare & Medicaid Services.

Approved: August 8, 2002.

Tommy G. Thompson,

Secretary.

[FR Doc. 02-29076 Filed 11-21-02; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 418

[CMS-1022-P]

RIN 0938-AJ36

Medicare Program; Hospice Care Amendments

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise existing regulations that govern coverage and payment for hospice care under the Medicare program. These revisions are required by the Balanced Budget Act of 1997 (BBA), the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA).

The BBA made changes to the time frame for completion of a physician's certification for admission of a patient;

the duration of benefit periods; the requirement that hospices make certain services available on a 24-hour basis; the required core services; the coverage of services specified in a patient's plan of care; and the payment of claims according to area. The BBA also established hospice payment rates for Federal fiscal years 1998 through 2002. BBRA amended those rates. BIPA further amended those rates and clarified the physician certification rule.

This rule would also add to existing regulations certain established Medicare hospice policies that currently are available only in policy memoranda. These policies clarify the regulations regarding the content of the certification of terminal illness and the admission to, and discharge from, a hospice.

This rule does not address the requirement for hospice data collection, the changes to the limitation of liability rules, or the changes to the hospice conditions of participation that were included in the BBA.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on January 21, 2003.

ADDRESSES: In commenting, please refer to file code CMS-1022-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Mail written comments (one original and three copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1022-P, Box 8010, Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and three copies) to one of the following addresses:

Hubert H. Humphrey Building, Room 443-G, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5-14-03, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

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

Comments mailed to the addresses indicated as appropriate for hand or

courier delivery may be delayed and could be considered late.

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

FOR FURTHER INFORMATION CONTACT:

Thomas Saltz, (410) 786-4480 or Carol Blackford, (410) 786-5909.

SUPPLEMENTARY INFORMATION: Inspection

of Public Comments: Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (410) 786-9994.

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

I. Background

A. Hospice Care

Hospice care is an approach to health care that recognizes that the impending death of an individual warrants a change in focus from curative care to palliative care, that is, relief of pain and other symptoms. The emphasis of hospice care is on the control of pain and the furnishing of services that enable the beneficiary to remain at home as long as possible with minimal disruption to normal activities. 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 caregivers, with the goal of making the individual as physically and emotionally comfortable as possible. Counseling and respite services are available to the family of the hospice patient. Hospice programs consider both the patient and the family as the unit of care.

B. Medicare Hospice Before the Balanced Budget Act of 1997

The Balanced Budget Act of 1997 changed and clarified numerous aspects of the Medicare hospice benefit including, the length of available benefit periods, the amount of annual updates, how local payment rates are determined, the time frame for physician certification, and what is considered a covered Medicare hospice service. Before explaining each change in detail, it is important to understand how the Medicare hospice benefit was structured prior to the BBA of 1997.

Section 1861(dd) of the Social Security Act (the Act) provides for coverage of hospice care for terminally ill Medicare beneficiaries who elect to receive care from a participating hospice. Beneficiaries are eligible to elect the Medicare hospice benefit if they are eligible for Medicare Part A; are certified as terminally ill by their personal physician, if they have one, and by the hospice medical director; and elect to receive hospice care from a Medicare-certified hospice. Section 1861(dd)(3)(A) of the Act defines terminally ill as a medical prognosis with a life expectancy of 6 months or less. This definition was clarified to provide for a life expectancy of "6 months or less if the illness runs its normal course" when we amended 42 CFR 418.3 in our December 11, 1990 final rule with comment period titled "Hospice Care Amendments: Medicare" (55 FR 50834).

A Medicare beneficiary who has elected the hospice benefit can receive care for specific lengths of time referred to as benefit periods. Under the Tax Equity and Fiscal Responsibility Act of 1982, hospice care was made available in three distinct benefit periods, the first two lasting 90 days, and the third lasting 30 days. The total amount of Medicare hospice coverage was 210 days. Because of the scientific difficulty in making a prognosis of 6 months or less, the 210-day limit was repealed by the Medicare Catastrophic Coverage Repeal Act of 1989 for services furnished on or after January 1, 1990. The benefit periods were restructured into two periods of 90 days duration, one period of 30 days duration, and a fourth period of unlimited duration. If a

beneficiary voluntarily left the program or was discharged from it, he or she forfeited the remaining days in the benefit period. If this occurred during the fourth benefit period, the beneficiary could never again receive the Medicare hospice benefit. A beneficiary in the fourth benefit period who became ineligible for hospice care services because he or she no longer met the eligibility requirements would return to normal Medicare coverage and would never be eligible for the Medicare hospice program, even if his or her condition once again became terminal. This provision was amended by the BBA, as discussed below.

Once a patient elects Medicare hospice care, the patient gives up the right to have Medicare pay for hospice care furnished by any hospice provider other than the one that he or she has selected, unless the selected hospice provider arranges for services to be furnished by another provider or if the patient elects to change providers. Also during the benefit period, the beneficiary gives up the right to receive any other Medicare payment for services that are determined to be related to his or her terminal illness or other related conditions or that are duplicative of hospice care. Medicare will continue to pay for a beneficiary's covered medical needs unrelated to the terminal condition.

The Medicare hospice benefit includes nursing services, medical social services, physician services, counseling services including dietary and bereavement counseling, short-term inpatient care including respite care, medical appliances and drugs, home health aide and homemaker services, physical therapy, occupational therapy, and speech-language pathology services. Medicare-certified hospices furnish care using an interdisciplinary team of people who assess the needs of the beneficiary and his or her family and develop and maintain a plan of care that meets those needs.

Under section 1814(i) of the Act, Medicare payment for hospice care is based on one of four prospectively determined rates that correspond to four different levels of care for each day a beneficiary is under the care of the hospice. The four rate categories are routine home care, continuous home care, inpatient respite care, and general inpatient care. The prospective payment rates are updated annually and are adjusted by a wage index to reflect geographic variation. The payment rules are in our regulations at part 418, subpart G, "Payment for Hospice Care."

II. Hospice Provisions of the Balanced Budget Act of 1997, the Balanced Budget Refinement Act of 1999, and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000

As mentioned above, the Balanced Budget Act of 1997 (BBA) included a number of provisions affecting the Medicare hospice benefit. Additionally, the Balanced Budget Refinement Act (BBRA) of 1999 and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA) of 2000 made some additional changes to the Medicare hospice benefit. This section will explain each change in detail and describe how these changes have been implemented. All of the BBA hospice provisions were implemented through a Program Memorandum (PM A-97-11) released in September 1997, which addresses all of the hospice-related BBA provisions, except the requirement for hospice data collection, the changes to the limitation of liability rules, the provision allowing contracting with physicians, and the new waivers for certain staffing requirements.

The provision allowing contracting with physicians and the new waivers for certain staffing requirements will be included in a proposed regulation to revise the hospice conditions of participation, which may be published in the near future. The limitation of liability rule changes were implemented through the Program Memorandum issued in September 1997. A hospice cost report for the hospice data collection was developed and issued in April 1999.

A. Payments for Hospice Services (Section 4441 of BBA)

Section 4441(b) of the BBA amended section 1814(i) of the Act to require hospice management to submit cost data for each fiscal year beginning with fiscal year 1999. A hospice cost report to collect this information was developed and issued in April 1999. To allow hospices enough time to prepare for the new requirement, the implementation of the hospice cost report was delayed until cost reporting periods beginning on or after April 1, 1999.

B. Payment for Home Hospice Care Based on Location Where Care Is Furnished (Section 4442 of the BBA)

Section 4442 of the BBA amended section 1814(i)(2) of the Act, effective for services furnished on or after October 1, 1997, to require that hospices submit claims for payment for hospice care furnished in an individual's home only on the basis of the geographic

location at which the service is furnished. Previously, local wage index values were applied based on the geographic location of the hospice provider, regardless of where the hospice care was furnished. Hospices were able to inappropriately maximize reimbursement by locating their offices in high-wage areas and actually delivering services in a lower-wage area. Applying the wage index values for rate adjustments on the geographic area where the hospice care is furnished would provide a reimbursement rate that is a more accurate reflection of the wages paid by the hospice for the staff used to furnish care.

C. Hospice Care Benefit Periods (Section 4443 of the BBA)

Section 4443 of the BBA amended sections 1812(a)(4) and 1812(d)(1) of the Act to provide for hospice benefit periods of two 90-day periods, followed by an unlimited number of 60-day periods. This amendment changed the previous hospice care benefit periods. Each period requires a physician to certify at the beginning of the period that the individual has a terminal illness with a prognosis that the individual's life expectancy is 6 months or less, should the illness run its normal course. Though it continues to be true that the remaining days in a benefit period are lost once a beneficiary revokes election of the hospice benefit or is discharged from the hospice, the restructured benefit periods will allow the beneficiary, or the hospice, to make this type of decision without placing the beneficiary at risk of losing hospice benefit periods in the future.

Section 4449 of the BBA indicated that the benefit period change applied to the hospice benefit regardless of whether or not an individual had made an election of the benefit period before the date of enactment. Therefore, beneficiaries who elected hospice before the BBA, and who, after the passage of the BBA, are discharged from hospice care because they are no longer terminally ill, could avail themselves of the benefit at some later date if they should become terminally ill again and otherwise meet the requirements of the Medicare hospice benefit. If the beneficiary had been discharged during the initial 90-day period, he or she would enter the benefit in the second 90-day period. If the discharge took place during the final 90-day period or any subsequent 60-day period, the beneficiary would enter the benefit in a new 60-day period. A beneficiary who had been discharged from hospice during the fourth benefit period before the enactment of the BBA would be

eligible to access the benefit again, if certified as being terminally ill, and would begin in a new 60-day period. The 90-day periods would not be available again, as amended section 1812(d)(1) of the Act still provides only for two 90-day periods during an individual's lifetime. There is no limit on the number of 60-day periods available as long as the beneficiary meets the requirements for the hospice benefit.

D. Other Items and Services Included in Hospice Care (Section 4444 of the BBA)

Section 1861(dd)(1) of the Act lists the specific services covered under the Medicare hospice benefit. Because the hospice provider is responsible for the palliation and management of the patient's terminal illness, it has always been Medicare's policy that Medicare hospice includes not only those specific services listed in Section 1861(dd)(1) of the Act but also any service otherwise covered by Medicare that is needed for the palliation and management of the terminal illness. Section 4444 of the BBA reiterates this policy by amending Section 1861(dd)(1) of the Act.

A new subparagraph "I" has been added to the list of covered hospice services in section 1861(dd)(1) of the Act, effective April 1, 1998. This new provision states that any other service that is specified in the plan of care, and for which payment may otherwise be made under Medicare, is a covered hospice service. As explained, this change underscores our previous construction of the law as requiring that the hospice is responsible for furnishing any and all services indicated as necessary for the palliation and management of the terminal illness, and related conditions, in the plan of care. A Medicare beneficiary who elects hospice care gives up the right to have Medicare pay for services related to the terminal illness, or related conditions, outside of the hospice benefit. Section 1861(dd)(1) of the Act contains a list of services and therapies covered under the Medicare hospice benefit. This list does not include services like radiation therapy, which are often furnished by hospices for palliative purposes. This change clarifies that these additional necessary services are covered under the hospice benefit and cannot be billed separately to Medicare.

E. Extending the Period for Physician Certification of an Individual's Terminal Illness (Section 4448 of the BBA)

Section 4448 of the BBA amended section 1814(a)(7)(A)(i) of the Act to eliminate the specific statutory time frame for the completion of a

physician's certification of terminal illness for admission to a hospice for the initial 90-day benefit period and to require only that certification be done "at the beginning of the period." A literal interpretation of "at the beginning of the period," that is, on the first day of the benefit period, would produce time frames that are more stringent than previous requirements. However, it appears that the congressional intent of this change was to give us the discretion, as we currently have with home health certifications, to require instead that hospice certifications be on file before a Medicare claim is submitted. Thus, section 4448 is titled "Extending the Period for Physician Certification of an Individual's Terminal Illness."

Before the BBA, hospices were required to obtain, no later than 2 calendar days after hospice care was initiated, written certification that a person had a prognosis of a terminal illness with a life expectancy of 6 months or less. For the first benefit period, if the written certification could not be obtained within the 2 calendar days following the initiation of hospice care, a verbal certification could be made within 2 days following the initiation of hospice care, with a written certification not later than 8 calendar days after care was initiated. For subsequent benefit periods, written certification was required no later than 2 calendar days after the first day of each benefit period.

The new certification requirements also apply to individuals who had been previously discharged during a fourth benefit period and are being certified for hospice care again to begin in a new 60-day benefit period. Also, due to the restructuring of the benefit periods, any individual who revoked, or was previously discharged from, the hospice benefit, and then reelects to receive the hospice benefit in the next available benefit period, will need to be recertified as if entering the program in an initial benefit period. This means that the hospice must obtain verbal certification of terminal illness no later than 2 days after care begins, and written certification before the submission of a claim to the fiscal intermediary.

F. Effective Date (Section 4449 of the BBA)

The provisions of the BBA discussed above, unless noted otherwise, became effective for services furnished on or after the date of enactment of the BBA, or August 5, 1997. Section 4444, the other services provision, was effective on April 1, 1998.

G. Clarification of the Physician Certification Requirement (Section 322 of BIPA)

Section 322 of BIPA amended section 1814(a) of the Act by clarifying that the certification of an individual who elects hospice "* * * shall be based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness." The amendment clarifies that the certification is based on a clinical judgment regarding the usual course of a terminal illness, and recognizes the fact that making medical prognostications of life expectancy is not always exact. This amendment at section 322(b) of BIPA clarifies and supports our current policy, which we are proposing to add to our regulations. The policy came about in response to Operation Restore Trust (ORT) and is discussed later in section III. B of this preamble. Briefly, ORT found that certification and recertification occurred without the documentation that would support the terminal illness prognosis. Accordingly, in 1995, we issued program memoranda requiring clinical findings and other documentation that support the medical prognosis. This documentation must accompany a certification and be filed in the patient's medical record.

We recognize that medical prognostications of life expectancy are not always exact, but the amendment regarding the physician's clinical judgment does not negate the fact that there must be a basis for a certification. A hospice needs to be certain that the physician's clinical judgment can be supported by clinical findings and other documentation that provide a basis for the certification of 6 months or less if the illness runs its normal course. A mere signed certification, absent a medically sound basis that supports the clinical judgment, is not sufficient for application of the hospice benefit under Medicare.

Section 322 of BIPA became effective for certifications made on or after the date of enactment, December 21, 2000.

III. Provisions of This Proposed Rule

We are proposing to make conforming changes to the Medicare hospice regulations to reflect the statutory changes discussed above. In addition, we are proposing to revise the regulation to reflect current policy on the documentation needed to support a certification of terminal illness, admission to Medicare hospice, and discharge from hospice. We are proposing to add one new requirement that would allow for discharges from

hospice for cause under very limited circumstances.

We propose to amend 42 CFR chapter IV by revising part 418.

A. Duration of Hospice care Coverage—Election Periods (§ 418.21)

In § 418.21, we are revising paragraph (a) to make hospice benefit periods available in two 90-day periods followed by an unlimited number of 60-day periods (requirement of section 4443 of the BBA).

B. Certification of Terminal Illness (§ 418.22)

We are revising the cross reference in § 418.22(a)(1) from "§ 418.21" to "§ 418.21(a)" and removing the phrase "for two, three, or four periods" and replacing it with "for an unlimited number of periods" to reflect the changes in the hospice care election periods (requirement of section 4443 of the BBA). We are revising the basic requirement at paragraph (a)(2) to state that the hospice must obtain written certification before it submits a claim for payment (requirement of section 4448 of the BBA), and we are proposing to revise the exception at paragraph (a)(3) to state that, if the hospice cannot obtain the written certification within 2 calendar days, it must obtain an oral certification within 2 calendar days, and the written certification before it submits a claim for payment. Oral certifications, therefore, which are necessary only if the hospice is unable to obtain written certification within 2 calendar days of the start of the benefit period, would be required for each benefit period rather than for just the initial 90-day period. We are maintaining our requirement for verbal physician's certification no later than 2 days after hospice care begins because we continue to believe that proper and timely assessment of a patient's condition is of critical importance both to the hospice, which becomes responsible for the patient, and to the patient, who must have a sound basis for choosing palliative rather than curative care.

As a condition of eligibility for a Medicare hospice program, an individual must be entitled to Medicare Part A and be certified as terminally ill. The Act also requires that this certification be made in writing by either the hospice medical director or the physician member of the interdisciplinary group, and by the attending physician, if the patient has one. However, the law does not explicitly discuss what information a hospice physician needs to consider

before making a certification of terminal illness.

Operation Restore Trust (ORT), a joint effort among the Centers for Medicare & Medicaid Services, the Office of the Inspector General, and the Administration on Aging to identify vulnerabilities in the Medicare program and to pursue ways to reduce Medicare's exposure to fraud and abuse, identified several areas of weakness in the hospice benefit, primarily in the area of hospice eligibility. In 1995, as a result of early ORT findings, we issued a letter to all Regional Offices and Regional Home Health Intermediaries (RHHIs) clarifying what should be included in a patient's medical record to support the certification of terminal illness. Subsequent ORT reports, and medical reviews conducted by RHHIs, have raised concerns about inappropriate certifications and recertifications and problems with a lack of documentation to support a prognosis of terminal illness. These reports and reviews found that certifications are being made for patients who are chronically ill but who are without complications or other circumstances that indicate a life expectancy of 6 months or less.

In response to these concerns, we are proposing to revise § 418.22(b) by adding introductory text, redesignating paragraph (b) as paragraph (b)(1), and adding an additional requirement for the content of certification as paragraph (b)(2). The introductory text will state that certification for the hospice benefit will be based upon the physician's or medical director's clinical judgment regarding the normal course of the individual's illness. In paragraph (b)(2), we propose requiring that specific clinical findings and other documentation supporting the medical prognosis accompany the written certification and be filed in the medical record as required under § 418.22(d).

C. Election of Hospice Care (§ 418.24)

In § 418.24, we are proposing to add to paragraph (c), "Duration of election," a new paragraph (c)(3) to state that 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 is not discharged from the hospice under the provisions of § 418.26. This addition would clarify that only revocation by the beneficiary or discharge by the hospice terminates an election.

D. Admission to Hospice Care (§ 418.25)

Also in response to concerns raised by ORT, we are proposing to establish general guidance on hospice admission procedures. Currently, there is no guidance in manuals or regulations regarding admission procedures. We are proposing to add a new § 418.25, "Admission to hospice care," which would establish specific requirements to be met before a hospice provider admits a patient to its care.

Paragraph (a) would permit a hospice to admit a patient only on the recommendation of the medical director in consultation with the patient's attending physician, if any. We realize that many hospice patients are referred to hospice from various "nonmedical" sources. This is entirely appropriate; however, it is the responsibility of the medical director, in concert with the attending physician, to assess the patient's medical condition and determine if the patient can be certified as terminally ill.

Paragraph (b) would require that the hospice medical director consider at least the following information when making a decision to certify that a patient is terminally ill: diagnosis of the patient's terminal condition; any related diagnoses or comorbidities; and current clinically relevant findings supporting all diagnoses.

E. Discharge From Hospice Care (§§ 418.26 and 418.28)

As with admission to hospice, the statute does not explicitly address when it is appropriate to discharge an individual from hospice care. Section 210 of the *Medicare Hospice Manual* (HCFA Pub. 21) explains that discharge is allowable only if the patient is no longer terminally ill or if the patient moves out of the service area.

We propose to add a new § 418.26, "Discharge from hospice care," to specify when a hospice may discharge a patient from its care. Paragraph (a), "Reasons for discharge," would specify that a hospice may discharge a patient if—

1. The patient moves out of the hospice's service area or transfers to another hospice;
2. The hospice determines that the patient is no longer terminally ill; or
3. The hospice determines, under a policy set by the hospice for the purpose of addressing "discharge for cause" that also meets the requirements discussed in the remainder of the new paragraph (a), that the patient's behavior is disruptive, abusive, or uncooperative to the extent that delivery of care to the patient or the ability of the hospice to

operate effectively is seriously impaired. When the hospice seeks to discharge a patient, we would require it to make a serious effort to resolve the problem(s) presented by the patient's behavior or situation; ascertain that the patient's proposed discharge is not due to the patient's use of necessary hospice services; document the problem(s) and efforts made to resolve the problem(s) and enter this documentation into the patient's medical records; and obtain a written physician's order from the patient's attending physician and hospice medical director concurring with the discharge from the hospice.

Since the inception of the Medicare hospice program, we have received inquiries from hospices regarding patients and their family members or primary caregivers who elected hospice but subsequently became uncooperative or hostile (including threats of physical harm and to the extent that hospice staff could not provide care to the patient) when the facilities attempted to provide care. In the absence of regulations or guidance from Medicare regarding these situations, hospices were uncertain as to their authority to act to resolve this type of problem. We offered informal guidance that if the hospice had made a conscientious effort to resolve the problem and had documented that effort, and the patient refused to revoke the benefit voluntarily, a discharge would be indicated. Failure to revoke the benefit could place the patient in a compromised position in which the patient would not be able to receive services from the hospice but would at the same time be unable to obtain services under the standard Medicare program because of his or her hospice status. An additional concern is the issue of daily payments being made to a hospice when no services are being provided. We are interested in commenter responses to this proposed regulation, particularly as to whether it is needed, and, if it is, whether there are sufficient protections for patients in the proposed rule.

Paragraph (b), "Effect of discharge," would specify that an individual, upon discharge from the hospice during a particular election period for reasons other than immediate transfer to another hospice is no longer covered under Medicare for hospice care and resumes Medicare coverage of the benefits waived under § 418.24(d). If the beneficiary becomes eligible for the hospice benefit at a future time, he or she would be able to elect to receive this benefit again.

Although the statute does not explicitly address when a hospice may discharge a patient from its care, we

realize that there are certain instances in which it is no longer appropriate for a hospice to provide care to a patient. We have attempted to capture those instances with our proposal; nevertheless, we are requesting that commenters share their experiences regarding situations that have arisen that would fall into one of our proposed categories.

A decision that a hospice patient is no longer terminally ill is generally not made during one assessment. However, once it is determined that the patient is no longer terminally ill, the patient is no longer eligible to receive the Medicare hospice benefit. Currently, the regulations do not provide any time for discharge planning between the determination that the patient is no longer terminally ill and discharge from the benefit. Since the BBA has ended the limitation on available benefit periods during a beneficiary's lifetime, we expect to see an increase in the number of beneficiaries being discharged from, or revoking, the hospice benefit because they can no longer be certified as terminally ill. However, it is common for these beneficiaries to remain in medically fragile conditions and in need of some type of medical services in order to remain at home. It is important that hospice providers consider these needs so that support structures can quickly be put into place should the patient's prognosis improve.

Therefore, we are proposing to add a paragraph (c), "Discharge planning," in new § 418.26. We would require at paragraph (c)(1) that the hospice have in place a discharge planning process that takes into account the prospect that a patient's condition might stabilize or otherwise change such that the patient cannot continue to be certified as terminally ill. Additionally, we are proposing at paragraph (c)(2) that the discharge planning process must ensure that planning for the potential of discharge includes consideration of plans for any necessary family counseling, patient education, or other services before the patient is discharged because he or she is no longer terminally ill.

Finally, § 418.28(b)(1) is revised to permit discharges for cause (under proposed § 418.26(a)(3)) if a patient refuses to sign a revocation statement. A signed revocation statement serves to protect hospice patients whose hospice may seek to discharge them because of possible higher costs associated with use of necessary services. Under current regulations, if a patient who otherwise would be discharged for cause were to refuse to sign a revocation statement,

the hospice would be in the anomalous position of receiving daily payments from Medicare for a person who cannot receive services. Earlier in this section, the implications for the hospice and the beneficiary were discussed. Paragraph (b)(1) would permit waiver of a signed revocation if one is not obtainable in cases of discharge for cause. It is our intention to take all comments into account prior to finalizing the "discharge for cause" policy. If implemented, our utmost concern is that there are sufficient patient protections in place to ensure appropriate delivery of care and, if needed discharge planning.

F. Covered Services (§ 418.202)

We would add a new paragraph (i) to § 418.202 to state that any other service that is specified in the patient's plan of care as reasonable and necessary for the palliation and management of the patient's terminal illness and related conditions, and for which payment may otherwise be made under Medicare, is a covered hospice service. This change was made by section 4444 of the BBA and was a clarification of long-standing Medicare policy.

G. Payment for Hospice Care (§§ 418.301, 418.302, 418.304, and 418.306)

In addition to reflecting the payment changes required by the BBA, we are proposing to add a new paragraph (c) to § 418.301, "Basic rules." This paragraph would restate the basic requirement, included in the provider agreement, that the hospice may not charge a patient for services for which the patient is entitled to have payment made under Medicare or for services for which the patient would be entitled to payment if the provider had completed all of the actions described in § 489.21. Since this requirement is currently included in the provider agreement, we would restate it in this part for clarification only.

We are adding a new paragraph (g) to § 418.302, "Payment procedures for hospice care," to provide that payment for routine home care and continuous home care would be made on the basis of the geographic location where the service is provided (requirement of section 4442 of the BBA).

We would also update the rules found at § 418.304, "Payment for physician services," to reflect current payment methodology for physician services under Medicare Part B. References to reimbursement based on reasonable charges would be replaced with references to the physician fee schedule. We would revise the first sentence of paragraph (b) to clarify that a specified

Medicare contractor pays the hospice an amount equivalent to 100 percent of the physician fee schedule, rather than 100 percent of the physician's reasonable charge, for those physician services furnished by hospice employees or those under arrangement with the hospice. We would also revise the second sentence of paragraph (c) to specify that 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 paid by the carrier under the procedures in subpart A, part 414 of chapter IV.

Finally, in § 418.306, "Determination of payment rates," we would revise paragraph (b)(3) and add new paragraphs (b)(4) and (b)(5) to set the payment rate in Federal fiscal years 1998 through 2002 as the payment rate in effect during the previous fiscal year increased by a factor equal to the market basket percentage increase minus 1 percentage point, with the exception that the payments for the first half of FY 2001 shall be increased 0.5 percent, and then increased an additional 5 percent over the above calculation. Payments for all of FY 2002 will be increased 0.75 percent.

IV. Collection of Information Requirements

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

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

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

Sections 418.22 and 418.26 of this proposed regulation contain information collection requirements that are subject to review by OMB under the PRA.

Section 418.22 Certification of Terminal Illness

The current collection requirements referenced in § 418.22 have been approved by OMB under approval number 0938–0302, with a current expiration date of January 31, 2003. However, this rule proposes a new collection requirement, which requires CMS to solicit comment on the new information collection requirement and resubmit 0938–0302 to OMB for review and approval, as a revision to a currently approved collection.

The newly proposed requirement as referenced under paragraph (b)(2) of this section stipulates that specific clinical findings and other documentation that support the medical prognosis must accompany the certification of terminal illness and must be filed in the medical record with the written certification as set forth in paragraph (d)(2) of this section.

While this requirement is subject to the PRA, we believe the burden associated with this requirement is exempt from the PRA as stipulated under 5 CFR 1320.3 (b)(2) and (b)(3) because the requirement is considered a reasonable and customary business practice and/or is required under State or local laws and/or regulations.

Section 418.26 Discharge From Hospice Care

The requirement referenced in paragraph (a)(3)(iii) of this section requires the documentation of the problem(s) related to the patient and efforts made to resolve the problem(s) and enter this documentation into the patient's medical records.

The requirement referenced in paragraph (a)(3)(iv) of this section requires that a written physician's order from the patient's attending physician and hospice medical director concurring with discharge from hospice care be obtained and included in the patient's medical record.

While these requirements are subject to the PRA, we believe the burden associated with these requirements is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2) and (b)(3) because the requirements are considered reasonable and customary business practices and/or are required under State or local laws and/or regulations.

If you have any comments on any of these information collection and record keeping requirements, please mail the original and three copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Information Services, Standards and Security

Group, Division of CMS Enterprise Standards, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850, ATTN: John Burke, CMS–1022–P; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, ATTN: Allison Eydt, CMS Desk Officer CMS–1022–P.

V. Regulatory Impact Analysis

The provisions of this proposed rule are based upon provisions in the BBA, BBRA, and BIPA, with statutorily-set timeframes, and have already been implemented through program memoranda. These include changes in election periods; timing requirements for written certification; covered services; payment based upon site of service; and annual payment update amounts. Other proposed provisions address documentation supporting certification; admission requirements; discharge from hospice; and clarification of current policy that has not previously been captured in regulations.

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 1980 Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any one year). We have determined that this rule is not a major rule for the reasons discussed below.

The RFA requires agencies to analyze options for regulatory relief of small businesses, nonprofit organizations, and government agencies. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or having revenues of \$25 million or less annually. For purposes of the RFA, all hospices are considered to be small entities. In 2001, there were approximately 2,277 Medicare-certified hospices. Of those 2,277, approximately 73 percent can be considered small

entities because they were identified as being voluntary, government, or other agency.

Given the general lack of hospice data and the unpredictable nature of hospice care, it is extremely difficult to predict the savings or costs associated with the changes contained in this proposed rule. Originally, we estimated the Medicare hospice rate reductions required by section 4441(a) of the BBA would result in a \$103 million savings to the Medicare program in FY 2002. Increases required by section 321 of BIPA, however, will add \$37 million to Medicare program costs. While it is likely that all of the Medicare-certified hospices considered to be small entities have been required to make changes in their operations in some way due to the implementation of these statutory provisions and proposed changes, this NPRM does not propose any additional changes that are likely to significantly impact the operations of hospice providers. For these reasons, we certify that this proposed rule will not have a significant effect on a substantial number of small entities. However, we have prepared the following analysis to describe the impacts of this rule. This analysis, in combination with the rest of the preamble, is consistent with the standards for analysis set forth by the RFA and EO 12866.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. This proposed rule largely codifies existing hospice requirements and will not result in a significant impact on a substantial number of small rural hospitals. Therefore, no analysis is required.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This proposed rule does not impose unfunded mandates, as defined by Section 202 of UMRA, as it will not result in the expenditure in any 1 year by either State, local or tribal governments, or by the private sector of \$110 million.

Executive Order 13132 establishes certain requirements that an agency

must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This proposed rule has no impact on State law. We have reviewed this proposed rule under the threshold criteria of Executive Order 13132 and we believe that it would not have substantial Federalism implications.

Section 1902(a)(13)(B) of the Act requires the Medicaid payment methodology for hospice care to be determined using the same methodology that is used for Medicare. State Medicaid programs with the optional Medicaid hospice benefit would be required to implement sections 4441(a) and 4442 of the BBA. We remain unaware of any impact of these provisions on State Medicaid programs since these provisions became effective. Nevertheless, it is possible that these payment-related provisions could impact particular State Medicaid programs. However, because each State Medicaid program is unique, it is impossible to quantify meaningfully, an estimate of the effect of the costs on State and local governments.

B. Anticipated Effects

1. Effects on Hospice Providers

Given the general lack of hospice data and the unpredictable nature of hospice care, it is extremely difficult to quantify the impact this proposed rule would have on hospice providers. Nevertheless, we have tried to estimate the impact of the following changes on hospice providers. In general, we believe that the effect of the proposed rule will have minimal economic impact on hospice providers or on the regulatory burden of small business. In the following sections we have indicated implementation actions already taken, and anticipated effects the proposed rules may have.

2. Effects on Payments

The BBA required hospice providers to bill for routine and continuous home care based on the geographic location where the service was provided. We expect that Medicare would experience some savings with this provision; however, it is impossible to predict the size of the savings attributable to this provision. These Medicare savings may reflect a cost to hospice providers. This BBA change has been implemented through program memoranda. This proposed rule merely codifies this statutorily required change.

3. Effects on Benefit Period Change

Medicare hospice is now available in two 90-day periods and an unlimited number of 60-day benefit periods. Because there is no longer a limit on the number of benefit periods available to a beneficiary, it is possible that this change would result in an increase in the number of revocations and reelections. However, we anticipate that this change would have a negligible effect on hospice providers. The change in benefit periods was implemented by a program memorandum issued shortly after passage of the BBA and has already been incorporated into hospice program operations.

4. Effects on Covered Services

The BBA clarified that the Medicare hospice benefit covers any service otherwise covered by Medicare and listed in the hospice plan of care as reasonable and necessary for the palliation and management of a terminal illness. This change should not generate any additional costs for Medicare hospices because it is merely a statutory clarification of existing Medicare policy. This clarification of covered hospice services was implemented through a program memorandum issued prior to the effective date set by the BBA, April 1, 1998 and is merely being codified by this regulation. It helped providers determine better the services they must provide.

5. Effects of Physician Certification

The requirement that a written certification of terminal illness for admission to a hospice for the initial 90-day benefit period be on file before a claim for payment is submitted would not impose any additional costs on hospice providers and removes the problem of obtaining the written certification according to a rigid timeframe. This requirement would provide hospices with more flexibility to establish cost-efficient procedures for obtaining the required certifications. However, the proposed expansion of the requirement for verbal certifications to every benefit period may impose costs on hospice providers. Before enactment of the BBA, verbal certifications were required within 2 days of the start of care during the first benefit period if a written certification could not be obtained within those 2 days. We are proposing to require that, absent written certification, verbal certifications of terminal illness be obtained within those 2 days for each benefit period. Although we believe the impact of this proposal would be negligible, it is difficult to estimate the exact size of the

impact of this proposal because some costs may be negated by the increased flexibility, and time, a hospice provider has in obtaining the required written certifications.

Additionally, we believe that the proposal to require that written certifications of terminal illness be accompanied by specific clinical findings and documentation supporting the prognosis would not impose any new costs on hospice providers. We released a policy memorandum in 1995 to all hospice providers, through the fiscal intermediaries, requesting that all hospices maintain documentation demonstrating a beneficiary's terminal status. Because it has been 6 years since we issued the policy calling for specific clinical findings and other documentation supporting the terminal prognosis, we do not anticipate that the requirement will alter hospices' current practices.

6. Effects on Admission to Hospice Care

We believe that the proposed regulation describing admission responsibilities would impose no additional burden upon hospices. The responsibilities were referred to in various regulations, manuals, program memoranda, and other correspondence; this regulation brings them together in an organized rule. ORT and OIG investigations and reviews found that admission activities were not always executed fully, or when done, they were not always documented. This proposed regulation would specify the consultation between the attending physician and the hospice and its medical director that normally does or should take place when a physician seeks hospice care for his or her patient. The regulation would also describe the consideration that the medical director gives, when deciding upon certification, to the patient's diagnosis, related diagnoses, medical findings that support those diagnoses, the over all medical management needs of the patient, and the attending physician's future plans for the patient. We do not believe any new costs are associated with these proposed requirements, and the 1995 policy memorandum had made clear hospice admission responsibilities and the need to document their execution. We found that the hospice provider community was generally pleased that CMS had issued the guidance, which alleviated previous problems associated with admission of beneficiaries to hospice care.

7. Effects on Discharge and Discharge Planning

This proposed regulation may add a small additional burden to hospices providing services to Medicare beneficiaries, but at the same time it also should reduce certain other burdens they may currently experience, particularly with respect to making appropriate discharges. In the absence of specific regulations, hospices have often been uncertain what to do when a patient appeared appropriate for discharge from the program. There was limited manual guidance, although following the ORT and OIG investigations, some additional information on the appropriate time to discharge patients was communicated to the hospice industry. Our proposal would incorporate discharge planning, a normal part of health care provision, into the hospice's care planning procedures. Regular, ongoing care planning, including the potential for discharge, has always been part of a hospice's responsibilities, and the regulation would simply recognize this responsibility. It is not a new additional burden.

Discharge for certain disruptive, abusive, or uncooperative patients would entail a small additional burden upon very few hospices, based on past discussions with some providers before preparation of this proposed rule. We believe the burden is small, because we have rarely received requests from hospices over the years for relief in cases involving this type of behavior. Elsewhere in this preamble, we have elicited input on this particular proposed rule, particularly with respect to protection of patients. We are aware of the burden that individual providers have had when faced with difficult patients, and this proposal would provide a way for them to resolve it, and, we believe, also lessen burdens currently experienced when trying to provide care to this type of patient.

The section of this proposed regulation that discusses the effect of discharge, that is, that a beneficiary discharged from hospice care immediately resumes full coverage under the regular Medicare program, has always been the law. However, it has not been stated in regulation in a straightforward manner, and doing so offers reassurance to both the beneficiary and the hospice that discharge from the hospice does not mean the loss of Medicare benefits. This section also assures a beneficiary that he or she may again elect hospice at any future time if he or she meets eligibility requirements.

C. Effects on Other Providers

We do not anticipate that this rule would have any effects on other provider types.

D. Effects on the Medicare and Medicaid Programs

As discussed above, it is very difficult to estimate the size of any savings to the Medicare program attributable to this proposed rule. We have estimated that the hospice rate reduction for FY 1998 through FY 2002, as required by section 4441(b) of the BBA, section 131(a) of BBRA, and section 321 of BIPA, would result in a total savings of \$108 million. Also, as discussed above, it is very difficult to estimate the size of any implementation costs to State Medicaid programs with optional Medicaid hospice benefits. However, it should be noted that the BBA provisions that State Medicaid programs are required to implement (rates of payment, payment based on location where care is furnished, other items and services, physician contracting) have been effective since August 5, 1997. Since that time, we have not received any correspondence from State Medicaid programs indicating that these provisions have had significant costs associated with implementation.

E. Alternatives Considered

Most of the proposed regulations are mandated requirements of the BBA, BBRA, and BIPA, and have already been implemented by CMS Program Memoranda, published in the month after passage of the BBA, and the month after the passage of BIPA. BBRA changes only concerned hospice payment amounts but did not affect the basic law. Discharge for cause will enable us to implement policies that permit hospices to act in those rare events that indicate the need, but with protection for the beneficiary included in the rules. Alternatively, hospices may continue to address this particular problem without certainty as to their authority in these special situations. Other proposed regulations represent current policies that have been implemented and recognized by the industry, clarification of current regulations, or suggested policies that the industry and CMS believe may help improve the Medicare hospice program.

F. Conclusion

The general lack of hospice data and the unpredictable nature of hospice care have made it extremely difficult to predict the savings or costs associated with the changes contained in this proposed rule. However, we believe that the proposed changes would create very

little, if any, new economic or regulatory burdens on hospice providers. These proposed changes are either statements of current policy or clarifications of policy that would benefit hospice providers. We believe that we have made every effort to mitigate the effects of these proposed changes on hospice providers.

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

VI. Response to Comments

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

List of Subjects in 42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and Record keeping requirements.

For the reasons set forth in the preamble, 42 CFR, Chapter IV, part 418 is proposed to be amended as set forth below:

PART 418—HOSPICE CARE

1. The authority citation for part 418 continues to read as follows:

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

Subpart B—Eligibility, Election and Duration of Benefits

2. In § 418.21, paragraph (a) is revised to read as follows:

§ 418.21 Duration of hospice care coverage—Election periods.

(a) Subject to the conditions set forth in this part, an individual may elect to receive hospice care during one or more of the following election periods:

- (1) An initial 90-day period;
- (2) A subsequent 90-day period; or
- (3) An unlimited number of subsequent 60-day periods.

* * * * *

3. In § 418.22, paragraphs (a) and (b) are revised to read as follows:

§ 418.22 Certification of terminal illness.

(a) *Timing of certification—(1) General rule.* The hospice must obtain written certification of terminal illness for each of the periods listed in

§ 418.21(a), even if a single election continues in effect for an unlimited number of periods, as provided in § 418.24(c).

(2) *Basic requirement.* Except as provided in paragraph (a)(3) of this section, the hospice must obtain the written certification before it submits a claim for payment.

(3) *Exception.* If the hospice cannot obtain the written certification within 2 calendar days, it must obtain an oral certification within 2 calendar days and the written certification before it submits a claim for payment.

(b) *Content of certification.*

Certification will be based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness. The certification must conform to the following requirements:

(1) The certification must specify that the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course.

(2) Specific clinical findings and other documentation that support the medical prognosis must accompany the certification and must be filed in the medical record with the written certification as set forth in paragraph (d)(2) of this section.

* * * * *

4. In § 418.24, paragraph (c) is revised to read as follows:

§ 418.24 Election of hospice care.

* * * * *

(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;

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

(3) Is not discharged from the hospice under the provisions of § 418.26.

* * * * *

5. New §§ 418.25 and 418.26 are added to read as follows:

§ 418.25 Admission to hospice care.

(a) The hospice admits a patient only on the recommendation of the medical director in consultation with the patient's attending physician, if any.

(b) In reaching a decision to certify that the patient is terminally ill, the hospice medical director must consider at least the following information:

(1) Diagnosis of the terminal condition of the patient.

(2) Other health conditions, whether related or unrelated to the terminal condition.

(3) Current clinically relevant findings supporting all diagnoses.

§ 418.26 Discharge from hospice care.

(a) *Reasons for discharge.* A hospice may discharge a patient if—

(1) The patient moves out of the hospice's service area or transfers to another hospice;

(2) The hospice determines that the patient is no longer terminally ill; or

(3) The hospice determines, under a policy set by the hospice for the purpose of addressing discharge for cause that meets the requirements of paragraphs (a)(3)(i) through (a)(3)(iv) of this section, that the patient's behavior is disruptive, abusive, or uncooperative to the extent that delivery of care to the patient or the ability of the hospice to operate effectively is seriously impaired. The hospice must do the following before it seeks to discharge a patient:

(i) Make a serious effort to resolve the problem(s) presented by the patient's behavior or situation.

(ii) Ascertain that the patient's proposed discharge is not due to the patient's use of necessary hospice services.

(iii) Document the problem(s) and efforts made to resolve the problem(s) and enter this documentation into its medical records.

(iv) Obtain a written physician's order from the patient's attending physician and hospice medical director concurring with discharge from hospice care.

(b) *Effect of discharge.* An individual, upon discharge from the hospice during a particular election period for reasons other than immediate transfer to another hospice—

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

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

(3) May at any time elect to receive hospice care if he or she is again eligible to receive the benefit.

(c) *Discharge planning.* (1) The hospice must have in place a discharge planning process that takes into account the prospect that a patient's condition might stabilize or otherwise change such that the patient cannot continue to be certified as terminally ill.

(2) The discharge planning process must include planning for any necessary family counseling, patient education, or other services before the patient is discharged because he or she is no longer terminally ill.

6. In § 418.28, paragraph (b)(1) is amended by adding the following sentence at the end of the paragraph.

§ 418.28 Revoking the election of hospice care.

* * * * *

(b) * * *

(1) * * * If a signed revocation is not obtainable by the hospice for a

discharge under § 418.26(a)(3), the requirement of the section may be waived.

Subpart F—Covered Services

7. In § 418.202, the introductory text is republished, and a new paragraph (i) is added to read as follows:

§ 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:

* * * * *

(i) Effective April 1, 1998, any other service that is specified in the patient's plan of care as reasonable and necessary for the palliation and management of the patient's terminal illness and related conditions and for which payment may otherwise be made under Medicare.

Subpart G—Payment for Hospice Care

8. Section 418.301 is amended by adding a new paragraph (c) to read as follows:

§ 418.301 Basic rules.

* * * * *

(c) The hospice may not charge a patient for services for which the patient is entitled to have payment made under Medicare or for services for which the patient would be entitled to payment, as described in § 489.21 of this chapter.

9. Section 418.302 is amended by adding a new paragraph (g) to read as follows:

§ 418.302 Payment procedures for hospice care.

* * * * *

(g) Payment for routine home care and continuous home care is made on the basis of the geographic location where the service is provided.

§ 418.304 [Amended]

10. In § 418.304, the following amendments are made:

a. In paragraph (b), the phrase "physician's reasonable charge" is removed and add in its place "physician fee schedule."

b. In paragraph (c), the phrase "subparts D or E, part 405 of this chapter" is removed and add in its place "subpart A, part 414 of this chapter."

11. In § 418.306, the introductory text of paragraph (b) is republished, paragraph (b)(3) is revised, and new paragraphs (b)(4) and (b)(5) are added to read as follows:

§ 418.306 Determination of payment rates.

* * * * *

(b) *Payment rates.* The payment rates for routine home care and other services included in hospice care are as follows:

* * * * *

(3) For Federal fiscal years 1994 through 2002, the payment rate is the payment rate in effect during the previous fiscal year increased by a factor equal to the market basket percentage increase minus—

(i) 2 percentage points in FY 1994;

(ii) 1.5 percentage points in FYs 1995 and 1996;

(iii) 0.5 percentage points in FY 1997; and

(iv) 1 percentage point in FY 1998 through FY 2002.

(4) For Federal fiscal year 2001, the payment rate is the payment rate in effect during the previous fiscal year increased by a factor equal to the market basket percentage increase plus 5 percentage points. However, this payment rate is effective only for the period April 1, 2001 through September 30, 2001. For the period October 1, 2000 through March 31, 2001, the payment rate is based upon the rule under paragraph (b)(3)(iv) of this section. The payment rate in effect during the period April 1, 2001 through September 30, 2001 is considered the payment rate in effect during fiscal year 2001.

(5) The payment rate for hospice services furnished during fiscal years 2001 and 2002 will be increased by an additional 0.5 percent and 0.75 percent, respectively. This additional amount will not be included in updating the payment rate as described in paragraph (b)(3) of this section.

* * * * *

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

Dated: June 3, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Dated: August 21, 2002.

Tommy G. Thompson,

Secretary.

[FR Doc. 02–29798 Filed 11–21–02; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Part 482**

[CMS–1224–P]

RIN 0938–AM01

Medicare Program; Nondiscrimination in Posthospital Referral to Home Health Agencies and Other Entities

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish a process for us to collect, maintain, and make available to the public, information about hospital referrals of Medicare patients to home health agencies (HHAs) and other entities with which the hospitals have a financial interest or which have a financial interest in the hospital. We would publicize this information in an effort to increase awareness regarding the availability of Medicare-certified HHAs and other entities to serve the Medicare population, and to inform beneficiaries of their freedom to choose among available Medicare-participating providers that are capable of furnishing the needed services.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on January 21, 2003.

ADDRESSES: In commenting, please refer to file code CMS–1224–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1224–P, PO Box 8014, Baltimore, MD 21244–8014.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) to one of the following addresses:

Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government

identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

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

FOR FURTHER INFORMATION CONTACT: Elizabeth Carmody, (410) 786–7533.

SUPPLEMENTARY INFORMATION: Inspection of Public Comments: Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (410) 786–7197.

Copies: Additional copies of the **Federal Register** containing this proposed rule can be made at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

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I. Background

Section 4321 of the Balanced Budget Act of 1997 (BBA), Pub. L. 105–33, was enacted by the Congress to improve the administration of the Medicare Program by enabling Medicare beneficiaries to make more informed choices about the providers from which they receive Medicare services. We believe that this provision was intended to address concerns that some hospitals were referring patients only to home health agencies (HHAs) in which they had a financial interest. Section 4321 of the BBA addresses both quality and program integrity concerns inherent in financial relationships among hospitals, HHAs, and other entities.

Section 4321(a) of the BBA requires that Medicare participating hospitals, as part of the discharge planning process, share with each beneficiary a list of