movement of injection or formation fluids into a USDW, provided that such wells meet the requirements of this section, even if the Director determines they have caused or may cause fluid movement into a USDW. Nothing in this section excuses such Class I municipal disposal wells from meeting all other applicable State and Federal requirements including 40 CFR 144.12(a).

(b) For purposes of this section, an existing Class I municipal disposal well is defined as a well for which a complete UIC construction permit application was received by the Director on or before December 22, 2005.

(c) For purposes of this section, the determination that a Class I municipal disposal well has caused or may cause movement of injection or formation fluids into a USDW may be made by the Director based on any relevant data available to him/her, including ground water monitoring data generated pursuant to regulatory requirements governing operation of Class I municipal disposal wells.

(d) In order for a Class I municipal disposal well to qualify for authorization to inject pursuant to paragraph (a) of this section, the Owner/Operator of that well shall:

(1) Develop and implement a pretreatment program that is no less stringent than the requirements of Chapter 62–625, Florida Administrative Code, or have no significant industrial users as defined in that chapter.

(2) Treat the injectate using secondary treatment in a manner that is no less stringent than the requirements of Florida Rule 62–600.420(1)(d), and using high-level disinfection in a manner that is no less stringent than the requirements of Florida Rule 62–600.440(5)(a)–(f), within five years after notification by the Director that the well has caused or may cause fluid movement into a USDW.

(e) Where the Director issued such notice for a well prior to December 22, 2005, in order for that well to qualify for authorization to inject pursuant to paragraph (a) of this section, the Owner/Operator shall:

(1) Develop and implement a pretreatment program that is no less stringent than the requirements of Chapter 62–625, Florida Administrative Code, or have no significant industrial users as defined in that chapter; and

(2) Treat the injectate using secondary treatment in a manner that is no less stringent than the requirements of Florida Rule 62–600.420(1)(d), and using high-level disinfection in a manner that is no less stringent than the requirements of Florida Rule 62–600.440(5)(a)–(f), within five years after December 22, 2005.

(f) Authorization to inject wastewater into existing Class I municipal disposal wells pursuant to this section is limited to Class I municipal disposal wells in Florida in the following counties: Brevard, Broward, Charlotte, Collier, Flagler, Glades, Hendry, Highlands, Hillsborough, Indian River, Lee, Manatee, Martin, Miami-Dade, Monroe, Okeechobee, Orange, Osceola, Palm Beach, Pinellas, St. Johns, St. Lucie, Sarasota, and Volusia.

■ 3. Section 146.16 is added to Subpart B to read as follows:

§ 146.16 Requirements for new Class I municipal wells in certain parts of Florida.

Prior to commencing injection, any Class I municipal disposal well in one of the counties identified in § 146.15(f) that is not an existing Class I municipal disposal well as defined in § 146.15(b) of this section shall meet all of the requirements for existing wells seeking authorization to inject pursuant to § 146.15.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 418

[CMS–1022–F]

RIN 0938–AJ36

Medicare Program; Hospice Care Amendments

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

ACTION: Final rule.

SUMMARY: This final rule revises existing regulations that govern coverage and payment for hospice care under the Medicare program. These revisions reflect the statutory changes 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). Additionally, these revisions reflect current policy on the documentation needed to support a certification of terminal illness, admission to Medicare hospice, and a new requirement that allows for discharges from hospice for cause under very limited circumstances.

This final 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.

The intent of this final rule is to expand the hospice benefit periods, improve documentation requirements to support certification and recertification of terminal illness, provide guidance on hospice admission procedures, clarify hospice discharge procedures, update coverage and payment requirements, and address the changing needs of beneficiaries, suppliers, and the Medicare program.

DATES: These regulations are effective on January 23, 2006.

FOR FURTHER INFORMATION CONTACT: Linda Smith, (410) 786–5650.

SUPPLEMENTARY INFORMATION:

I. Background

A. Hospice Care

Hospice care means a comprehensive set of services described in 1861(dd)(1) of the Social Security Act (the Act), identified and coordinated by an interdisciplinary team to provide the physical, psychosocial, spiritual, and emotional needs of a terminally ill patient and family members or both as denoted in a specific patient plan of care.

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. Section 1861(dd) of 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. Prior to the BBA of 1997, if a beneficiary voluntarily left the program or was discharged from it, he or she forfeited the remaining days in the benefit period. When 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 then 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.

The BBA of 1997 amended the election and benefit period procedures to state that once a patient elects the Medicare hospice benefit, 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 would 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 42 CFR 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

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 additional changes to the Medicare hospice benefit. Program Memorandum (PM A–97–11), released in September 1997, implemented most of the hospice-related BBA provisions.

The limitation of liability rule changes were implemented through the Program Memorandum (PM A–97–11), issued in September 1997. A hospice cost report for the hospice data collection requirement was developed and issued in April 1999.

A. Payments for Hospice Services (Section 4441 of the 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 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, required hospices to 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 provides 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, were discharged from hospice care because they were no longer terminally ill, were able to avail themselves of the benefit at some later date if they became terminally ill again and otherwise met 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. 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 reiterated this policy by amending section 1861(dd)(1) of the Act to add a new subparagraph ''I'' 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. 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. It requires only that certification be done ''at the beginning of the period.'' In accordance with our understanding of congressional intent, this change, (for example, as indicated by the title of section 4448), was made to extend the period for physician certification of the terminal illness by allowing hospices the discretion to require that hospice certifications are on file before a Medicare claim is submitted.

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. Under the new certification requirement, certification must be done ''at the beginning of the period.'' To protect the beneficiaries, we are requiring that the hospice obtain written certification before it submits a claim for payment.

This new certification requirement also applies 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 of the BBA, 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 clarified 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 of BIPA clarifies and supports our current policy. In the early 1990's, we discovered that in many cases certification and recertification occurred without the documentation that would support the terminal illness prognosis. Accordingly, in 1995, we issued program memoranda requiring clinical information 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. However, 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 information and other documentation that provide a basis for the certification of 6 months or less if the illness runs its normal course. A 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.

Requirements for Issuance of Regulations

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final rule. Section 902 of the MMA also states that the timelines for these regulations may vary but shall not exceed 3 years after publication of the preceding proposed or interim final rule except under exceptional circumstances.

This final rule finalizes provisions set forth in the November 22, 2002 proposed regulation with some changes based on public comments (67 FR 70363). In addition, this final rule has been published within the 3-year time limit imposed by section 902 of the MMA. Therefore, this final rule is in accordance with the Congress' intent to ensure timely publication of final regulations.

III. Provisions of the Proposed Regulations

In the proposed rule published November 22, 2002 (67 FR 70363), we proposed to amend 42 CFR Chapter IV by revising part 418. We proposed to make conforming changes to the Medicare hospice regulations to reflect the statutory changes, to revise the regulation to reflect current policy and to clarify requirements regarding the documentation needed to support a certification of terminal illness and the admission to and discharge from a Medicare hospice. We proposed to add one new requirement that would allow for discharges from hospice for cause under very limited circumstances.

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

In § 418.21, we proposed to revise 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 proposed to revise the cross reference in § 418.22(a)(1) from ''§ 418.21'' to ''§ 418.21(a)'' and remove the phrase ''for two, three, or four periods'' and replace 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 proposed to revise 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 proposed 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. Therefore, oral certifications, 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 proposed to maintain 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 proposed 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 would state that certification for the hospice benefit would 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 proposed requiring that clinical information 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 proposed to add to paragraph (c), ''Duration of election,'' a new paragraph (c)(3) to state that an election to receive hospice care would 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 proposed to establish general guidance on hospice admission procedures. Currently, there is no guidance in manuals or regulations regarding admission procedures. We proposed to add a new § 418.25, ''Admission to hospice care,'' which establishes 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 information 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. The Internet Online Manual (IOM) Medicare Benefit Policy Manual, Section 20.2.1 Hospice Discharge, 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 proposed 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. Before 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.

Paragraph (b), ''Effect of discharge,'' specifies 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. 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 proposed to add a paragraph (c), ''Discharge planning,'' in the new requirement at § 418.26. We 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 that the patient cannot continue to be certified as terminally ill. Additionally, we proposed 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, we proposed to revise § 418.28(b)(1) to permit discharges for cause (under proposed § 418.26(a)) 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 position of receiving daily payments from Medicare for a person who cannot receive services. Paragraph (b)(1) would permit waiver of a signed revocation if one were not obtainable in cases of discharge for cause. 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 proposed to 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 proposed 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 proposed to add 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 based on the geographic location where the service is provided (requirement of section 4442 of the BBA).

We proposed to 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 proposed to 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 also proposed to 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 provisions in 42 CFR Part 414 Subpart B.

Finally, in § 418.306, ''Determination of payment rates,'' we proposed to revise paragraph (b)(3) and to 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 were increased by 0.75 percent.

IV. Analysis of and Responses to Public Comments

We received a total of 27 timely public comments in response to the November 22, 2002 proposed rule (67 FR 70363). Some of the organizations we received letters from were hospice providers, national stakeholder and advocacy groups, national and State hospice associations, and other health care providers and suppliers. All public comments were reviewed and grouped by the same or related topics. The comments and our responses are summarized below.

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

Comment: A commenter stated that the regulations should make clear that if a beneficiary revokes the benefit and there are unused days remaining in the benefit period, the beneficiary is free to re-elect hospice before those unused days pass.

Response: Section 418.26(b)(3) specifically states that the individual ''may at any time elect to receive hospice care if he or she is again eligible to receive the benefit.'' Section 418.28(c)(3) also contains similar language.

Comment: One commenter requested that the new benefit period rules apply to State Medicaid programs that offer hospice.

Response: This would be up to individual States, who generally follow Medicare hospice rules.

Comment: A commenter asked us to state in the final rule that there is no 6-month limit on hospice eligibility as long as there is documentation to support medical reviews of cases when this happens.

Response: We do not believe this language needs to be included in the final rule. The 6-month rule applies to eligibility for the hospice benefit, including a patient's prognosis and life expectancy. Medical reviews are not automatic in the event that a patient lives longer than 6 months, and could occur at any point during an individual's time in hospice including less than 6 months if this review were indicated.

B. Certification of Terminal Illness (§ 418.22)

Comment: A few commenters believe that the proposed rule would require oral certifications for each benefit period, and that oral certification is required from the medical director and the attending physician for all benefit periods, a new and unnecessary burden.

Response: This is not correct. An oral certification is only needed if no written certification is obtained within 2 days. This change in regulations implements a BBA provision that the Congress intended to ease the burden of obtaining a written certification within 2, or at the latest, 8 days after the start of the initial benefit period. Now, the written certification is required before a hospice submits a claim for payment. Therefore, oral certification will be required if the written certification cannot be obtained within 2 days following the start of the benefit period. In fact, the rules for certification for periods following the initial period are unchanged. Section § 418.22(c), the regulation concerning the initial certification and those that followed, was not part of the proposed changes published on November 22, 2002 (67 FR 70363). This regulation requires the attending physician's (if there is one) certification for the initial period. Subsequent periods only require certification by the hospice's medical director or the physician member of the hospice IDG.

Comment: Several commenters are concerned that language calling for ''specific clinical findings and other documentation'' at § 418.22(3)(b)(2) could end up with requirements that would become excessively specific and cause access problems due to a perception that exacting documentation requirements must be met; or that additional tests must be performed, beyond what already will have sufficiently established that eligibility is met. Commenters suggested that physician experience and not simply lab or pathology reports be recognized.

Response: It appears that the word ''specific'' may be skewing the intention of the regulation. This rule is being added to formalize policy that came in response to OIG/ORT findings in the mid-1990s, when a number of admissions to hospices were happening with little or no documentation that supported a certification for hospice. We expect that a hospice patient's medical record would contain sufficient information to support the certification of the individual as having a terminal illness with a life expectancy of 6 or fewer months, if the illness runs its normal course. We believe it is reasonable to expect documentation to support the certification. We are removing the word ''specific'' and changing ''findings'' to ''information'' so that the phrase would read ''clinical information and other documentation.'' Section 322 of BIPA called for the physician's ''clinical judgment,'' and this regulation simply asks that it be supported.

Comment: A commenter stated that the best approach to certification might be for the attending physician to refer patients he or she believes eligible, and for the medical director to exercise his or her best judgment regarding concurrence.

Response: The Medicare statute is clear about the responsibility of the hospice's medical director to certify, along with the attending physician for the initial benefit period, the individual as eligible for hospice.

Comment: Two commenters believe we were compromising the intent of BIPA by requiring oral certifications for each benefit period, requiring a hospice to expend additional resources without any obvious benefit. One commenter believes this is a new requirement. Another commenter indicated that it ignores Congressional intent.

Response: In a sense, this is a new requirement, but it protects and ensures timely medical care for the beneficiary as well as significantly eases the written certification burden on the hospice. The hospice regulations have always required written certification at the start of each benefit period. The Congress made no indication that this rule should end. Now, all that is required, if a written physician certification cannot be completed within 2 calendar days after a period begins, is that an oral certification be obtained. Previously a written certification was required within 2 days for every period after the initial benefit period, or the hospice would be faced with the possibility of a claim being denied. We are following Congressional intent, in that the Congress indicated that the written hospice certification rule should follow the home health rule, and be on file before a claim is submitted.

Comment: A commenter believes that clinical information and documentation do not need to accompany the certification, and urged that we delete ''accompany'' in the requirement at § 418.22(b)(2), replacing it with simply a requirement that the information be in the medical record. The commenter believes that if documentation had to accompany the certification, care could be delayed or even denied, and an unnecessary burden would be placed upon the hospice and other providers. Several commenters pointed out that frequently hospices obtain certifying information over the phone from the referring physician, which is then recorded and placed in the patient's medical record.

Response: We believe that clinical information and documentation are critical to the certification decision. We recognize that some documentation may physically arrive at the hospice and be placed in the medical record after the start of care; however, that should not mean that the information does not come to the attention of the hospice and be included in the certification and admission process. The attending physician may well report clinical information by telephone or interview, with written documents to arrive later. It is the information needed for the hospice's IDG to develop the initial plan of care for the new patient, and therefore we would expect the information to accompany, in some fashion, the certification, although some of it may not arrive physically at the hospice until later. We are revising this final rule to indicate that clinical information may initially arrive verbally and is documented in the patient's medical record as part of the hospice's assessment of eligibility for hospice.

Comment: A commenter objected to oral certification within 2 days after the start of each benefit period, believing it is unnecessary record keeping.

Response: Certification no later than 2 days after the start of each benefit period is not a new requirement. Past regulations required that certification be in writing no later than 2 days after the start of care for all periods after the initial period. The oral certification is a way to protect and ensure timely medical care for the beneficiary as well as easing the written certification burden on the hospice. This final rule requires oral certification (if needed) for all benefit periods, and in writing before a claim for the period is submitted.

Comment: A few commenters stated that it was burdensome and unnecessary to require clinical information and documentation as part of the certification that supports the physician's clinical judgment that the individual is terminally ill with a prognosis of 6 months or less to live if the illness runs its normal course. There were suggestions that BIPA's amendment of the statute, which provides for ''certification based on the physician's or medical director's clinical judgment * * *'' was sufficient, without any supporting documentation at the time of certification. It was noted that prognosis is inexact at best, and that we seemed to be requiring accurate predictions (with possible penalties for failure to be precise).

Response: As discussed in the preamble of the November 22, 2002 proposed rule (67 FR 70363), the Medicare statute does not explicitly describe what a physician needs to consider before certifying a patient for hospice. In that preamble, we cited early ORT findings (which were partly based upon other OIG and intermediary medical reviews of patient records) as clearly indicating a need for requirements that certifications be supported by clinical findings and documentation. (Elsewhere in this preamble, we discuss the replacing of the word ''findings'' with ''information'' in the final rule.) Our 1995 letters to RHHIs clarified expectations for supporting documentation, and this information was widely disseminated to the hospices and the hospice industry. Response to our effort was positive. At that time, claims were coming under closer scrutiny, and failure to find documentation in medical records that supported certification and the need for hospice caused denial of claims. CMS has sent out widely disseminated letters that made it clear that Medicare supports accessibility to the hospice benefit. The letters recognized that prognosis is not an exact science, and that the impact of a hospice's services may sometimes lead to brief periods of improvement. Nevertheless, it is reasonable to expect that information supporting physician certifications be provided to ensure that patients beginning hospice are appropriate for this type of care.

Comment: One commenter stated that written certifications did not need to be obtained by the hospice before submission of claims for periods following the initial period and could be obtained later.

Response: A written certification has been required by statute since the inception of the Medicare hospice program.

Comment: There was a comment that certification of the terminal illness should be based on either the attending physician's certification or the hospice's medical director's certification.

Response: This is a statutory requirement. Section 1814(a)(7)(A) of the Social Security Act requires that both the hospice's physician (either the medical director or physician member of the interdisciplinary group) and the attending physician (if the patient has one) must certify patients for the Medicare hospice benefit for the initial period. For subsequent benefit periods, the hospice physician alone may certify patients for the hospice benefit. The attending physician does not have sole or surrogate power to certify for admission for any benefit period.

C. Election of Hospice Care (§ 418.24)

No comments were received.

D. Admission to Hospice Care (§ 418.25)

Comment: A commenter suggested that the medical director alone certify patients for hospice.

Response: Though the medical director or physician member of the hospice interdisciplinary group must certify for each election period, the attending physician (if any) is also

required, by statute, to do so for the first election period.

Comment: Some commenters believe the regulation would require the attending physician to participate in all certifications that may be required, and that it imposes a barrier to obtaining hospice care. Further, it would subvert the role of the IDG. It would also increase costs unnecessarily, since some patients are near death by time of admission.

Response: This is not correct. An attending physician (if the patient has one) does certify for the initial period, but is not required or expected to do any subsequently needed certifications. We would expect the attending physician to be consulted by the medical director or IDG if he or she has maintained significant involvement in the case.

Comment: A commenter believes this rule negates the role of the IDG in the admission process.

Response: The role of the IDG is not changed by this rule. Regulations at § 418.22(c)(1)(i), which includes the physician member of the interdisciplinary group as a party who may certify terminal illness, remain the same.

Comment: A commenter believes that the November 22, 2002 proposed rule requires excessive involvement by the Medical Director in the patients' admission to hospice, such as physically seeing the patient before admission, making telephone calls to the attending physician, and obtaining original history and physical reports.

Response: Currently, to be admitted to hospice, the patient must meet the eligibility requirements at § 418.20(b) ''certified as being terminally ill in accordance with § 418.22.'' It is the physician's responsibility to assess the patient's medical condition and determine if the patient can be certified as terminally ill. This is reflected in Section 418.22(c)(i) and (ii), Sources of Certification, which states that for the initial 90-day period, certification statements must be obtained from ''the medical director of the hospice or the physician member of the hospice interdisciplinary group; and the individual's attending physician if the individual has an attending physician.'' The new requirements at § 418.25 provides clarification of the physician's responsibilities as it relates to the admission process.

Comment: Some commenters suggested that this final rule would require the medical director to consult directly with the attending physician, and that it would be a poor and expensive use of the director's time. Some commenters stated that it would be a needless impediment that would add delays to the start of hospice care. One commenter stated that the final rule required every piece of medical documentation be in the hands of the medical director before an admission decision is made. One commenter stated that the hospice nurse, while obtaining pre-admission information, would be the more appropriate individual to obtain an attending physician's input in the admission process.

Response: It is not our intent to require a face-to-face or any type of direct consultation between the Director and the attending physician. We are revising the language to indicate that the medical director has considered patient information from the attending physician that may be obtained through consultation, or through information obtained indirectly. Information could be obtained through the hospice nurse or others who would bring the attending physician's knowledge of the patient to the medical director when the admission decision is being made. We also note that the medical documentation does not necessarily need to be physically in the hands of the medical director, but that the information presented is considered in the decision. The medical reports may arrive later for retention in the patient's medical record.

Comment: A commenter suggested that the proposed rule required an attending physician to be consulted, which would be impossible if the patient did not have one.

Response: The proposed rule included the phrase ''if any'' following ''attending physician'' but preceded by a comma. We have made ''if any'' a parenthetical phrase after attending physician to make it clearer that we recognize that there may not be an attending physician in all cases.

Comment: One commenter is concerned that small hospices that use volunteer medical directors would be forced to hire a Medical Director at a big expense. The commenter believes that volunteers would be reluctant to offer their time because consultation with attending physicians at the time of admission would require more time than they would be willing to provide. Other commenters believe that hospices, especially small ones with part-time medical directors with separate private practices, will face considerable increased costs if medical directors were forced to consult with attending physicians.

Response: We cannot know whether this final rule would cause volunteer physicians to cease participating in any particular hospice program, or what additional costs a hospice would face with respect to its part-time medical directors. However, no matter what the status of the hospice medical director—employee or volunteer—that individual (or the physician member of the IDG) has always had a responsibility to review the appropriateness of admission of new patients to hospice. The ORT/OIG reports from the mid-1990s investigations made it clear that we need to make sure that certifications were not simply a physician signature upon a document alone, but that there was documentation supporting the admission decision that had been considered. The medical director's certification is an essential part of the admission procedure, and the director considering the attending physician's knowledge of the patient is part of the certification decision. As we discussed elsewhere in the preamble, the consultation need not be direct, but the attending physician's input should be considered in the admission process.

Comment: A commenter stated that the medical director must submit documentation regarding his or her consideration of the documentation.

Response: The medical director would only need to document that the pertinent clinical information had been considered in the certification process. The documentation includes a diagnosis of the patient's terminal condition; any related diagnoses or comorbidities; and current clinically relevant findings supporting all diagnoses.

Comment: A commenter objected to § 418.25(b) describing the information that should be considered by the medical director when certifying a patient.

Response: We believe that this final rule clarifies the expectation that underlies the basis for making a significant decision about an individual accepting his or her terminal condition and the treatment plans that are to come. It is information that should be considered, and we do not think that the final rule should be modified.

Comment: One commenter opposes this admission section of the proposed regulations entirely, citing election and certification as the only requirements for beginning hospice. The commenter believes that the admission rules would make it impossible for a hospice to admit certain individuals for care for a terminal illness that does not meet the Medicare eligibility requirements for the benefit, but for whom the hospice would not submit claims to Medicare.

Response: As we explained in the preamble to the proposed rule (67 FR 70367), this regulation would establish guidance on hospice admission

procedures. It clarifies and supports the election and certification rules by describing the process by which a medical director must certify that a patient is terminally ill and, thus, admit that patient to the hospice. In addition, the admission rules, along with election and certification rules would not necessarily pertain to an individual that does not meet Medicare eligibility rules but whom the hospice otherwise decides to offer services to without cost to Medicare.

E. Discharge From Hospice Care (§ 418.26)

We received some comments that indicated that a discharge for cause rule offered helpful guidance in cases where patients consistently refused to permit the hospice to visit or deliver care, or it was dangerous for staff to visit the home, or when the patient repeatedly left the service area. Other commenters asked for specificity in the regulations regarding circumstances when the discharge for cause rule might apply. We do not believe it is possible to do this without creating either an excessively lengthy regulation or one that due to over-specificity would unintentionally take the flexibility that the hospice may need to act. We do plan to offer some guidance and examples in the hospice manual.

Comment: Some commenters want family added along with the patient as a source of problems that could be a reason to consider a discharge for cause. Commenters cited examples such as threats from the patient's family, or drug stealing and drug dealing by members of the patient's household.

Response: We agree, and have amended the proposed rule to take other persons (which would include family) in the patient's home into account. To the extent that the situation interferes with the ability of the hospice staff to provide care efficaciously, it may be appropriate to discharge the patients. However, we would expect the hospice to make every effort to rectify the situation before ending its services, with documentation of what transpired in the case. Alternative suggestions and referrals for care should be presented to the patient and his or her caregiver before ending services.

Comment: A commenter suggested that failure on the part of the patient to follow the plan of care be identified as a reason for discharge. Instances of the patient going to the emergency room without first contacting the hospice were cited, particularly with respect to financial issues where the patient would be responsible for care not arranged for through the hospice.

Response: We do not think that single instances of the patient/family going to the emergency room without prior authorization from the hospice would necessarily be a valid reason for discharge. Failure to follow important clinical features of the POC may be a reason to consider discharge, but a panicked reaction to an emergency should not be, by itself, a reason to terminate services. It is important for the patient and family to be educated before the start of care that hospice entails certain limits in the way care will be provided once hospice services begin, among them being restrictions on obtaining care outside those provided or arranged for by the hospice, and the patient's potential liability for care received without the hospice's involvement. It is particularly important that the patient and caregiver be instructed on what to do in a crisis or emergency.

Comment: Some commenters believe that it would be very difficult to obtain a patient's attending physician's signature when discharging a patient for cause, and that in any event many attending physicians cease following their patients after hospice begins. Some patients never had an attending physician. Other commenters worry that an attending physician could override an IDG decision, when the attending physician's opinion was not needed or that in the case of an attending physician who disagreed with discharge, it would place him or her in a compromised position with his or her patient. Further, the commenter stated that it is ultimately the hospice's responsibility to decide upon discharge of patients.

Response: If there is no attending physician involved in a patient's care, then such a requirement would seem to create a problem. At the same time, a discharge for cause is a serious matter where we believe the patient needs some protection from a hospice that may behave unethically and try to discharge a patient because he or she may require more attention or care than the hospice wished to offer. If there is an attending physician, his or her opinion matters. However, to reduce a burden that the proposed rule might have created if it were finalized, we are revising the requirement at § 418.26(b) to read, ''Prior to discharging a patient for any reason listed in subsection (a), the hospice must obtain a written physician's discharge order from the hospice medical director. If the patient has an attending physician involved in his or her care, the physician should be consulted before discharge and his or her view included in the discharge note.'' This would help ensure that the attending physician's position on discharge for cause is taken into account, as well as giving the attending physician an opportunity to participate in post-discharge planning for the patient.

Comment: Some commenters suggested that either the attending physician or medical director could sign a discharge order.

Response: We cannot accept this suggestion. It is the responsibility of the hospice to make this decision, just as it is the hospice's decision to admit the new patient. Elsewhere in this preamble, we have indicated that the final rule has been revised to indicate that the attending physician is to be consulted and his or her views included in the discharge note.

Comment: Commenters want the discharge-planning rule made conditional upon the possibility that there will be time to plan, or that planning only be done when possible, since some patients may need immediate discharge because they are no longer terminally ill. Requests were made for a time frame for determining stability requiring discharge.

Response: The rule requires that the hospice have in place a process ''that takes into account the prospect that a patient's condition might stabilize or otherwise change''. We do not expect that a discharge would be the result of a single moment that does not allow time for some post-discharge planning. Rather, we would expect that the hospice's IDG is following their patient, and if there are indications of improvement in the individual's condition such that hospice may soon no longer be appropriate, then planning should begin. If the patient seems to be stabilizing and the disease progression has halted, then it could be the time to begin preparing the patient for alternative care. Discharge planning should be a process, and planning should begin before the date of discharge. We have tried to avoid prescriptive time frames for discharge planning, since we have long been aware that merely the attention that hospice services give to a patient can have a beneficial effect, creating the impression that the individual may no longer be ''actively dying'' and therefore ineligible for the Medicare hospice benefit. Therefore, we cannot offer a specific number of days or weeks that a patient may be stable and thus not eligible. We see this issue as one requiring physician/IDG judgment and would only ask that the judgment be supported by documentation in the medical record indicating the reason

why hospice should continue if there seems to be improvement such that discharge is under consideration.

Comment: A commenter wanted the discharge of a patient who moves out of the service area or who transfers to another hospice to include patients who temporarily leave the hospice's service area without notifying or making arrangements with the hospice.

Response: If the patient transfers to another hospice, then the assumption is that arrangements have been made, and end and start dates of care have been worked out. This is not a temporary move, and discharge issues should not arise. Concerning patients who leave the hospice service area temporarily, this issue should have been addressed by the hospice at the time of admission when the hospice explains to the patient the waiver of benefits that occur upon election of the hospice benefit. If the hospice patient leaves the service area and attempts to obtain care for his or her terminal condition for which hospice was elected, then the patient assumes financial responsibility for this care. It is not necessarily a reason to discharge a patient unless there is a repeated pattern of such activity and it interferes with the care that the hospice plan of care calls for. The hospice should counsel the patient regarding the consequences of obtaining care from sources other than the hospice. The patient may even decide to revoke the benefit under the circumstances.

Comment: A commenter does not believe a discharge plan should be required for all patients, since live discharges are rare. Imposing this requirement for every patient would be an unnecessary and costly burden.

Response: We believe that the commenter may have misunderstood the purpose of the proposed rule. A hospice would need to have a process in place should the condition of a patient show indications that hospice possibly may no longer be the appropriate treatment for that individual. We do not expect that every patient will have a discharge plan prepared. However, should a hospice patient's condition seem to be improving (beyond just brief periods of improvement that sometimes occur simply because the individual is receiving attention and some symptom relief), the hospice IDG should have a discharge planning process available in order to help make plans for the individual's discharge and follow-up care as may be needed. We would expect most patients would not have a discharge plan ever; however, when indicated, the hospice would have the ability to begin the process timely.

Comment: A commenter believes that requiring a written physician's order for discharge of a patient, ignored the role of the IDG, including the attending physician if he or she is participating.

Response: We agree about the essential role of the IDG, and we would expect their participation in any discharge decisions. However, it is the commonly accepted practice for a physician to sign an admission or discharge order in hospitals. Similarly, it is the hospice physician who signs a certification for hospice care in order to begin care, and that individual also would consequently be the one to sign the discharge order. Elsewhere in this preamble, we have advised that an attending physician would not be required to sign discharge papers.

Comment: A commenter urged that in cases of discharge for cause the patient should be notified of this possible action.

Response: We agree, and have revised the regulation to reflect this suggestion.

Comment: A commenter wants the beneficiary advised of appeal rights when a discharge for cause is being considered. One commenter noted the potential for misuse of the discharge for cause rule to discharge high-cost patients.

Response: There are no specific appeal rights for the beneficiary regarding such considerations. However, for the protection of the beneficiary, we added to the regulation, a provision that the beneficiary must be notified, by the hospice, that discharge for cause is being considered.

Comment: A commenter suggested that we monitor, analyze, and identify ways to reduce discharge for cause, and perhaps then establish a forum for sharing best practices on maintaining hospice care for difficult patients.

Response: We appreciate the suggestion and will consider it for future program evaluations.

Comment: A commenter complained that having a physician sign a discharge order was creating an additional paperwork burden.

Response: We see the signing of a discharge order in the patient's medical record as part of the physician's administrative activities. Signing the order would simply be the final action at the end of discharge process.

Comment: Some commenters believe that it was inappropriate to ask the hospice, in considering a discharge for cause, to ''ascertain that * * * is not due to * * * use of necessary hospice services,'' and that it would be difficult to prove a negative that the use of services was not a factor in discharge. Commenters did agree that use of necessary services would not be an appropriate reason to discharge.

Response: We believe that this requirement is appropriately in this section of the rule. It is one of our concerns that discharge for cause could be a rule that offers opportunity for abuse, and we want to make it clear that the hospice needs to make sure that it is planning to discharge a patient because of behavior issues, not time or effort or cost factors in providing services to a particular individual. We believe that ascertaining that discharge is not due to the use of necessary services is simply a reminder that some of a hospice's patients require more services. This fact should not influence a discharge decision.

Comment: One commenter suggested that the regulations should not list any reasons for a cause discharge and instead the hospice should set its own policy for discharge for cause. This was based upon the assertion that it is impossible to set forth rules that could address every possible circumstance that would be a reason to seek a cause discharge.

Response: We agree that it is impossible to list every possible reason that an individual might be discharged under this rule. That being said, we believe that the circumstances under which this type of discharge could be considered are adequately addressed by the rule we published. The types of behavior discussed in the rule that seriously impair the hospice's ability to operate effectively and provide care to the patient and the requirements imposed on the hospice are necessary to place some parameters on discharges for cause.

Comment: One commenter is concerned that the hospice would be responsible for post-discharge care of patients discharged for cause, when generally these would be patients that it had already found to be a problem to the extent that it could not provide needed services.

Response: We recognize that it may be very difficult to implement post-discharge care plans for a patient that has proven to be disruptive, abusive, or uncooperative to the extent that services cannot be provided, but post-discharge care would not be the responsibility of the hospice. The hospice would engage in and prepare for after hospice care, but it is up to the patient (and the patient's supporters) to take advantage of other sources of care after discharge. Though not entirely analogous, it is similar to a physician prescribing medication, but it is the responsibility of the patient to take the medication, even after the

physician has fully informed the patient of the importance of doing so.

F. Revoking Election of Hospice Care (§ 418.28)

Comment: A commenter believes that the waiver of a signed revocation when a patient revocation cannot be obtained in cases of discharge for cause should be placed in the section of regulations addressing discharge. The commenter stated that it is confusing to have it in its present location as it mixes discharge and revocation. The commenter also pointed out that a discharge for cause is not revocation. Revocation is voluntary, and mixing it with discharge for cause is confusing and unnecessary.

Response: We agree that this proposal is unneeded, and it has been deleted from the final rule.

G. Covered Services (§ 418.202)

Comment: Commenters objected to ''other covered services'' applying to ''related conditions'' (to the terminal illness), and asked that it be removed from the proposed rule. The commenters feared it would be misinterpreted to mean that the hospice would be responsible for services not related to the terminal illness.

Response: A hospice has always been responsible for the care of the patient's terminal illness and related conditions, and this rule should not be interpreted to mean what the commenter fears, that is, that the hospice provides care unrelated to the terminal illness. At the same time, if the hospice staff notices, for example, that the patient has an eye infection that is unrelated to the terminal illness, then sound health care practices suggest that the hospice staff refer that person to his or her doctor for treatment. Commenters should review the hospice regulation at 42 CFR 418.402, which addresses this concern when it states that ''* * * services not considered hospice care include * * * treatment of an illness or injury not related to the individual's terminal condition.''

Comment: One commenter asked how ''covered services'' might be interpreted by contractors reviewing claims, and whether the lack of specificity defining these services could cause denial of payment if ''covered services'' were determined to be non-covered.

Response: As we discussed in the preamble to the proposed rule, the BBA clarified and codified what had been a Medicare rule, but had not always been well understood: that a ''service that is specified in the patient's plan of care as reasonable and necessary for the palliation and management of the terminal illness and related conditions, and for which payment may otherwise be made under Medicare, is a covered hospice service.'' The decision as to whether a patient requires and receives any particular service from the hospice is, as before, the responsibility of the hospice. A medical review by a contractor would not necessarily consider whether an item was not required and therefore subject to a denial or payment, but rather whether the patient had received the appropriate necessary care for his or her particular terminal condition. Hospice payment is a prospectively-set daily payment to the hospice, and is made without regard to the cost of care on any particular day, nor with regard to the total cost of care during the entire time period that the hospice cares for the patient.

Comment: One commenter believes that the phrase ''otherwise covered by Medicare'' would result in limitations on what patients could receive by way of care, since items not covered by the regular Medicare program would not be available due to this phrase.

Response: The BBA expressly used the cited phrase in amending the law and in a congressional document, indicating that Medicare services that had not previously been specified in section 1861(dd)(1) of the Act were indeed to be made available under the hospice benefit if determined to be medically necessary and ordered in the plan of care.

Comment: A commenter believes that hospices would use this phrase to use unqualified and untrained persons to provide services.

Response: Hospices must meet conditions of participation, which require that their staff be qualified to provide the particular service the patient needs.

Comment: The American Association for Respiratory Care asked whether respiratory therapy, when part of a hospice patient's plan of care, is a Medicare covered hospice service.

Response: Respiratory therapy would be a covered hospice service if the hospice decides its patient requires the service. Provision of the service would be paid for out of the hospice daily rate made to the hospice.

Comment: One commenter suggested that psychologists be recognized as equivalent practitioners to physicians for purposes of payment for mental health services required by a hospice patient. The commenter argued that as an otherwise covered Medicare service, certain patients could benefit from a psychologist's specialized training, but because of the high cost of these services, a hospice would avoid arranging for them. This would be due to the fact that payment would come out of the hospice's daily rate, a limited source of payment for all needed hospice services for individual patients.

Response: The Medicare law, with respect to hospice, only recognizes physicians as defined by statute, that is, medical doctors and osteopaths, and we therefore limit separate additional payments to those practitioners. If a hospice recognizes that its terminally ill patient requires the services of a psychologist, it is free to arrange for it.

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

Comment: A commenter requested that § 418.301(c) indicate that hospices pay for medical services not related to the hospice-covered terminal illness. Another commenter asked that we clarify that hospices are only responsible for the care and services related to the terminal illness.

Response: Conditions not related to the terminal illness may be covered under the regular Medicare program, a right that the beneficiary does not lose when hospice is elected. Even though other non-hospice care may be written into the hospice's plan of care to address care and services not related to the terminal illness, which help assure proper care to the patient, the hospice's responsibility is for care and services related to the terminal illness. Of course, the hospice would be expected to make the proper referrals when needed.

Comment: One commenter asked about the change proposed in § 418.304(b), where the phrase ''physician's reasonable charge'' is replaced by ''physician fee schedule''. The commenter wanted to know if this change was the change discussed in the preamble of the proposed rule.

Response: The change in the regulation is the same one discussed in the preamble of the proposed rule.

I. Miscellaneous Comments

Comment: Some commenters believe that we were tightening up the 6-month prognosis, and that it would make physicians more reluctant to refer patients to hospice. Commenters stated that physicians are ''terrible'' at determining prognoses. They feared they would be exposed to scrutiny and penalty if they failed to make accurate prognoses.

Response: As we have noted elsewhere in this section, we know that ''prognosis'' indicates expectancy. It does not connote exact predictions regarding the expected date of death of an individual with a terminal illness. We merely want the certification of the

patient for hospice care to be accompanied by documentation that supports the appropriateness of the hospice benefit.

Comment: One commenter seems concerned by references to ORT, and what was perceived as a disregard for the intent of Congress to make hospice more accessible.

Response: We believe that ORT and other investigations by the OIG are what helped guide the Congress in changes affecting the Medicare hospice benefit, and that we adhered to this effort to make the benefit more accessible. Payments for hospice care increased in response to industry complaints that payments were inadequate, but payment based upon the location at which the services were provided (the individual's home) made it more appropriate in that it reflected the wages paid in the home's location rather than the high cost area where the hospice's home office might be located. The unlimited number of benefit periods permitted the hospice industry and all potential patients to no longer worry that an individual might live into a fourth but final benefit period and then be forced out of hospice care because of improvement in health, only to face permanent loss of access to hospice care in the future because of pre-BBA rules. Physician certification rules were eased, but as discussed elsewhere, the Congress gave no indication that it was dissatisfied with our clarification of requirements that a physician certification of terminal illness be supported by documentation. In addition, the growth of hospice since the ORT/OIG investigations indicates that our clarification has not adversely affected the industry, considering the increases in patient enrollment and Medicare payments for the care.

Comment: A commenter asked about relief from the 24-hour registered nurse requirement for respite care.

Response: This issue is being taken into consideration as CMS drafts the new Hospice Conditions of Participation.

V. Provisions of the Final Regulations

For the most part, this final rule incorporates the provisions of the proposed rule. The provisions of this final rule that differ from the proposed rule are as follows and changes are based on public comments to provide clarifying language:

Certification of Terminal Illness (§ 418.22)

(a) *Timing of certification: (3) Exception.* Added, ''after a period begins'' to clarify timeframe for written certification within 2 days.

(b) *Content of certification:* Deleted the term ''specific'' and changed ''findings'' to ''information.'' Also added, ''Initially, the clinical information may be provided verbally, and must be documented in the medical record and included as part of the hospice's eligibility assessment.''

Admission To Hospice Care (§ 418.25)

(a) Added clarifying language ''or with input from'' the patient's attending physician and added parentheses around the phrase ''if any.''

Discharge From Hospice Care (§ 418.26)

(a) *Reasons for discharge.*

(3) Added clarifying language ''(or other persons in the patient's home)'' to address public comment that the patient's family may be the problem necessitating a discharge for cause. Also added the following language ''(i) Advise the patient that a discharge for cause is being considered'' to address the public comment that there should be requirements for notification to beneficiaries.

(b) Renumbered and revised proposed paragraph (a)(3)(iv) for clarity as follows ''Prior to discharging a patient for any reason listed in subsection (a), the hospice must obtain a written physician's discharge order from the hospice medical director. If a patient has an attending physician involved in his or her care, this physician should be consulted before discharge and his or her review and decision included in the discharge note.''

Revoking the Election of Hospice Care (§ 418.28)

Deleted proposed change to § 418.28(b)(1).

Payment for Physician Services (§ 418.304)

As a technical correction we are replacing the language ''reasonable charges'' with physician fee schedule: to reflect the current payment methodology. Additionally, the cross-reference to ''subparts D or E, Part 405 of this chapter'' will be changed to ''subpart B, Part 414 of this chapter.''

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-day notice in the **Federal Register** and solicit public comment when 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 final regulation contain information collection requirements that are subject to review by OMB under the PRA.

Certification of Terminal Illness (§ 418.22)

The current collection requirements referenced in § 418.22 have been approved by OMB under approval number 0938–0302, with a current expiration date of September 30, 2006. However, this rule imposes 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 imposed requirement as referenced under paragraph (b)(2) of this section stipulates that clinical information 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 (b)(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.

Discharge From Hospice Care (§ 418.26)

Paragraph (a)(3)(iv) of this section requires documentation of the problem(s) related to the patient and efforts made to resolve the problem(s) into the patient's medical records.

Paragraph (b) of this section requires that a written physician's discharge order from the hospice medical director and the decision of the patient's attending physician (if any) 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.

We have submitted a copy of this final rule to OMB for its review of the information collection requirements described above. These requirements are not effective until they have been approved by OMB.

If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following: Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Attn: Melissa Musotto, CMS–1022–F, Room C5–11–04, 7500 Security Boulevard, Baltimore, MD 21244–1850; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Carolyn Lovett, CMS Desk Officer. Comments submitted to OMB may also be e-mailed to the following address: e-mail: *Carolyn_Lovett@omb.eop.gov* or faxed to OMB at (202) 395–6974.

VII. Regulatory Impact

The provisions of this final 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 final rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). 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. 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 by having revenues of $6 million to $29 million in any 1 year. Individuals and States are not included in the definition of a small entity. For purposes of the RFA, 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 final rule. Originally, we estimated the Medicare hospice rate reductions required by section 4441 of the BBA would result in a $120 million savings to the Medicare program in FY 2002. Increases required by section 321 of BIPA, however, added $150 million to Medicare program costs, and increases required by section 131 of BBRA added another $20 million in costs, for a net of $50 million in costs for that fiscal year. 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 final rule does not set forth any additional changes that are likely to significantly impact the operations of hospice providers. For these reasons, we certify that this final 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 Executive Order 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 604 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 final 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 final 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 final rule has no impact on State or local governments. We have reviewed this final rule under the threshold criteria of Executive Order 13132 and we believe that it will 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 final rule will 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 final 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 final rule 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 final 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 will result in an increase in the number of revocations and re-elections. However, we anticipate that this change will 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 before the April 1, 1998 effective date set by the BBA and is merely being codified by this regulation. It helped providers to better determine 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 will not impose any additional costs on hospice providers and removes the problem of obtaining the written certification according to a rigid timeframe. This requirement will provide hospices with more flexibility to establish cost-efficient procedures for obtaining the required certifications. However, the 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 requiring 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 requirement would be negligible, it is difficult to estimate the exact size of the impact of this requirement 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 requiring that written certifications of terminal illness be accompanied by clinical information and documentation supporting the prognosis will 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 10 years since we issued the policy calling for clinical information 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 final rule describing admission responsibilities will 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 final rule specifies 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 final rule also describes the consideration that the medical director gives when deciding upon certification, to the patient's diagnosis, related diagnoses, medical information that support those diagnoses, the overall 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 requirements, and the 1995 policy memorandum had made clear the hospice admission responsibilities and the need to document their execution. We found that the hospice provider community was generally pleased that we had issued the guidance, which alleviated previous problems associated with admission of beneficiaries to hospice care.

7. Effects on Discharge and Discharge Planning

This final rule 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 final rule 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 will entail a small additional burden upon very few hospices, based on past discussions with some providers before preparation of this final 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. In the

preamble to the proposed rule, we elicited input on this particular final 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 regulation 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 final rule 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.

8. Effects on Other Providers

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

9. 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 final rule. We have estimated that the hospice rate reduction as required by section 4441 of the BBA, temporary increases in hospice care payments for FY 2001 and FY 2002 due to section 131 of BBRA, and a 5 percent increase in hospice payments due to section 321 of BIPA, would result in a net savings of $80 million for FY 1998–2002 and an overall net cost of $120 million for FY 1998–2007. Given that after FY 2001 the annual costs attributable to section 321 of BIPA exceed the annual savings attributable to section 4441 of BBA, there are net costs in the out-years attributable to these two provisions. Below is a table indicating the year-by-year costs and savings attributable to the various provisions.

COSTS ASSOCIATED WITH THE VARIOUS HOSPICE PROVISIONS

FY	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
BBA Sec. 4441	−20	−40	−70	−90	−120	−130	−140	−140	−150	−160
BBRA Sec. 131	.....	.....	.....	10	20	.....	.....	.....	.....	
BIPA Sec. 321	.....	.....	.....	80	150	160	170	180	200	210
Total Costs	−20	−40	−70	0	50	30	30	40	50	50

All dollar figures are in millions and rounded to the nearest $10 million. Costs are shown as positive, savings as negative.
BBA Sec. 4441: Payments for Hospice Services.
BBRA Sec. 131: Temporary increase in payment for hospice care.
BIPA Sec. 321: 5% Increase in Payment.

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.

C. Alternatives Considered

Most sections of this final rule 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 sections of this final rule 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.

D. Conclusion

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined that this final rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

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 final rule. However, we believe that these changes will create very little, if any, new economic or regulatory burdens on hospice providers. These 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 changes on hospice providers.

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

List of Subjects in 42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

■ For reasons set forth in this preamble, the Centers for Medicare & Medicaid Services amend 42 CFR chapter IV as follows:

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, 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, after a period begins, 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) Clinical information 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. Initially, the clinical information may be provided verbally, and must be documented in the medical record and included as part of the hospice's eligibility assessment.

* * * * *

■ 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; 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, or with input from, 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 information 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 (or other persons in the patient's home) 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 for cause:

(i) Advise the patient that a discharge for cause is being considered;

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

(iii) Ascertain that the patient's proposed discharge is not due to the patient's use of necessary hospice services; and

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

(b) *Discharge order.* Prior to discharging a patient for any reason listed in paragraph (a) of this section, the hospice must obtain a written physician's discharge order from the hospice medical director. If a patient has an attending physician involved in his or her care, this physician should be consulted before discharge and his or her review and decision included in the discharge note.

(c) *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.

(d) *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.

Subpart F—Covered Services

■ 6. 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

■ 7. 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.

■ 8. 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]

■ 9. In § 418.304, the following changes are made:

■ a. In paragraph (b), the phrase ''physician's reasonable charge'' is

removed and is replaced with ''physician fee schedule.''

■ b. In paragraph (c), the phrase ''subparts D or E, part 405 of this chapter'' is removed and the phrase ''subpart B, part 414 of this chapter'' is added in its place.

■ 10. 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 is increased by an additional 0.5 percent and 0.75 percent, respectively. This additional amount is not 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 Program)

Dated: May 24, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: October 11, 2005.

Michael O. Leavitt,

Secretary.

[FR Doc. 05–23078 Filed 11–21–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

49 CFR Part 10

FAA Accident and Incident Data System Records Expunction Policy

AGENCY: Federal Aviation Administration, DOT.

ACTION: Policy statement.

SUMMARY: The Federal Aviation Administration (FAA) has adopted a policy which, when implemented, will result in the expunction of airman identities from certain FAA accident and incident records.

DATES: This policy is effective November 22, 2005, with implementation as discussed herein.

FOR FURTHER INFORMATION CONTACT: Joseph R. Standell, Aeronautical Center Counsel, Aeronautical Center (AMC–7), Federal Aviation Administration, 6500 S. MacArthur, Oklahoma City, OK 73169. Telephone (405) 954–3296.

SUPPLEMENTARY INFORMATION:

Background

Under sections 40101, 40113, and 44701 of the U.S. Transportation Code, as amended, 49 U.S.C. 40101, 40113 and 44701, the FAA may maintain records of aviation accidents and incidents containing identifying information of individual airmen if safety in air commerce or air transportation and the public interest require. These records include all accidents that were investigated by the FAA and incidents reported to or investigated by the FAA. Part 10 of the Department of Transportation Regulations, 49 CFR 10.1 *et seq.,* sets forth the conditions for maintenance and access to records pertaining to individuals.

Presently, written accident and incident records are destroyed in accordance with the applicable retention guidelines contained in FAA Order 1350.15C. Certain essential information is extracted from written accident and incident records and maintained in the Accident and Incident Data System (AIDS).

Currently, computer based electronic AIDS records are maintained indefinitely by the FAA. The custodian of AIDS is the Aviation Data Systems Branch, AFS–620, at the Mike Monroney Aeronautical Center, Oklahoma City, Oklahoma. AIDS records may be accessed by FAA personnel at the FAA's Headquarters in Washington, DC and the FAA's field and regional offices. See, System of Records DOT/FAA 847, 65 FR 19527 (April 11, 2000). One of the reasons the FAA maintains these records is for safety related statistical research. Aviation Safety Inspectors may also use these records to determine whether an airman should be re-examined. AIDS records are considered to be basic qualification information and may be released to the public pursuant to the routine uses listed in DOT/FAA 847.

In 1989, the FAA conducted a System Safety and Efficiency Review (SSER) of its General Aviation Compliance and Enforcement Programs. The SSER review team comprised both FAA personnel and representatives of various industry organizations, including the Aircraft Owners and Pilots Association, the Experimental Aircraft Association, and the National Business Aircraft Association. The establishment of an accident and incident expungement policy was one of the many topics discussed during the System Safety and Efficiency Review. However, no accident and incident expungment policy was implemented at that time.

From 1996 until the present, the FAA has expunged the identity of airmen from AIDS records on an ad hoc basis, where it was determined that their identity no longer served a relevant purpose. Those determinations were made in response to individual requests for correction of accident or incident record pursuant to the Privacy Act, 5 U.S.C. 552a. Absent a request for correction of records under the Privacy Act, the record remained in AIDS indefinitely. There has been growing concern within the FAA that this practice is unfair to those airmen who do not know their identity may be removed from an AIDS record by making a request under the Privacy Act.

In 2003, the FAA reevaluated its policy of indefinitely retaining AIDS records on individuals, and subsequently adopted a policy of expunging certain electronic AIDS records. This policy is explained in detail herein. This policy applies to individuals who have been identified in electronic AIDS records. This policy applies to individuals who hold airman certificates, as well as to those who do