

5. *Regulatory Flexibility Act*

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal that is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

VII. List of Subjects in 30 CFR 926

Intergovernmental relations, Surface mining, Underground mining.

Dated: January 26, 1995.

Charles E. Sandberg,

Acting Assistant Director, Western Support Center.

For the reasons set out in the preamble, Title 30, Chapter VII, Subchapter T of the Code of Federal Regulations is amended as set forth below:

PART 926—MONTANA

1. The authority citation for Part 926 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

2. Section 926.15 is amended by adding paragraph (l) to read as follows:

§ 926.15 Approval of amendments to State regulatory program.

* * * * *

(l) With the exception of the word "reasonable" in the last sentence of MCA 84-4-226(8), concerning right of entry to inspect prospecting operations under notices of intent, revisions of the following statutes, as submitted to OSM on June 16 and July 28, 1993, and as supplemented with explanatory information on July 28, 1994, are approved effective February 1, 1995:

82-4-203, MCA, subsections (14), (16), (21), (23), (29), (34), (35), and (36), definitions; repeal of 82-4-224, MCA, surface owner consent; 82-4-226, MCA, subsections (1), (2), (3), (5), (6), and (8), prospecting permits and notices of intent 82-4-227, MCA, subsections (1), (2), (3), (7), (8), (9), (10), (11), (12), and (13), permit approval/denial criteria.

3. Section 926.16 is amended by revising the introductory paragraph, by adding paragraphs (g) through (j), and by removing the parenthetical at the end of the section to read as follows:

§ 926.16 Required program amendments.

Pursuant to 30 CFR 732.17(f)(1), Montana is required to submit to OSM by the specified date the following written, proposed program amendment, or a description of an amendment to be proposed that meets the requirements of SMCRA and 30 CFR Chapter VII and a timetable for enactment that is consistent with Montana's established administrative or legislative procedures.

* * * * *

(g) By April 3, 1995, Montana shall revise MCA 82-4-227(10), or otherwise modify its program, to require that no permit or major permit revision may be issued unless the coal conservation plan affirmatively demonstrates that failure to conserve coal will be prevented.

(h) By April 3, 1995, Montana shall revise MCA 82-4-226(8), or otherwise modify its program, to prohibit prospecting under notices of intent when more than 250 tons of coal are to be removed.

(i) By April 3, 1995, Montana shall revise MCA 82-4-266(8) to delete the word "reasonable" in the final sentence.

(j) By April 3, 1995, Montana shall revise MCA 82-4-226(8), or otherwise modify its program, to provide authority for the inspection of monitoring equipment and prospecting methods for prospecting conducted under notices of intent, and access to and copying of any records required by the Montana program on such prospecting operations, at any reasonable time without advance notice upon presentation of appropriate credentials, and to provide for warrantless right of entry for prospecting operations conducted under notices of intent, to be no less effective in meeting SMCRA's requirements than 30 CFR 840.12 (a) and (b).

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

RIN-0720-AA18

[DoD 6010.8-R]

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Hospice Care

AGENCY: Office of the Secretary, DoD.

ACTION: Final rule.

SUMMARY: This final rule revises DoD 6010.8-R which implements the Civilian Health and Medical Program of the Uniformed Services. The rule establishes a hospice benefit for the terminally ill that offers an alternative to traditional therapeutic treatment which may no longer be appropriate or desirable. Hospice care is palliative rather than curative, generally emphasizing home care rather than institutional care, and treating the social, psychological, spiritual, and physical needs of the entire family. **EFFECTIVE DATE:** This final rule is effective June 1, 1995.

ADDRESSES: Office of the Civilian Health and Medical Program of the Uniformed Service (OCHAMPUS), Program Development Branch, Aurora, CO 80045-6900.

FOR FURTHER INFORMATION CONTACT: David Bennett, Program Development Branch, OCHAMPUS, Aurora, Colorado 80045-6900, telephone (303) 361-1094.

SUPPLEMENTARY INFORMATION: In FR Doc. 93-21950, appearing in the **Federal Register** on September 10, 1993 (58 FR 47692), The Office of the Secretary of Defense published for public comment a proposed rule establishing a hospice benefit under CHAMPUS.

Background

The Defense Authorization Act for FY 1992-93, Public Law 102-190, directed CHAMPUS to provide hospice care in the manner and under the conditions provided in section 1861(dd) of the Social Security Act (42 U.S.C. 1395x(dd)). This section of the Social Security Act sets forth coverage/benefit guidelines, along with certification criteria for participation in a hospice program. Since it is Congress' specific intent to establish a benefit identical to that of Medicare, CHAMPUS has adopted the provisions currently set out in Medicare's hospice coverage/benefit guidelines, reimbursement methodologies (including national hospice rates and wage indices), and certification criteria for participation in

the hospice program (42 CFR Part 418, Hospice Care).

Under these provisions CHAMPUS will provide palliative care to individuals with prognoses of less than 6 months to live if the illness runs its normal course. The benefit is based upon a patient and family-centered

model where the views of the patient and family or friends figure predominantly in the care decisions. This type of care emphasizes supportive services, such as pain control and home care, rather than cure-oriented services provided in institutions that are

otherwise the primary focus under CHAMPUS.

CHAMPUS will use the following national Medicare hospice rates for services provided on or after October 1, 1994, through September 30, 1995, along with the wage and nonwage components of each:

	National rate	Wage component	Nonwage component
Routine Home Care	\$90.51	\$62.19	\$28.32
Continuous Home Care	528.30	362.99	165.31
Inpatient Respite	93.63	50.68	42.95
General Inpatient	402.67	257.75	144.92

The rates are based on a cost-related prospective payment method subject to a "cap" amount and will be adjusted annually by the Medicare hospital market basket inflation factor for services rendered on or after October 1 of each fiscal year. These national payment rates will be adjusted for regional wage differences by using appropriate Medicare area wage indices. The hospice will be reimbursed for an amount applicable to the type and intensity of the services furnished to the beneficiary on a particular day. The Medicare statutory cap amount for the cap year ending October 31, 1994, is \$12,846. Annual adjustments to the cap amount will be the same as Medicare.

Hospice care is viewed as the most cost-effective form of treatment for the terminally ill. The benefit lowers costs by reducing or eliminating inpatient days, unnecessary tests, and expensive curative therapies. The national rate system is designed to reimburse the hospice for the costs of all covered services related to the treatment of the beneficiary's terminal illness, including the administrative and general supervisory activities performed by physicians who are employees of, or working under arrangements made with, the hospice.

Review of Comments

As a result of the publication of the proposed rule, the following comments were received from interested associations and agencies.

Comment 1. One commentor felt that it would be unfair for OCHAMPUS to apply Medicare aggregate reimbursement limitations to individual hospices since the CHAMPUS beneficiary population is only a fraction of the Medicare population. It was their contention that the volume of Medicare patients is sufficiently large to allow for the development of average inpatient stay, and average cost per patient, whereas the volume of CHAMPUS

patients in any one hospice would be so small as to potentially result in a skewed average; e.g., a hospice may have a small percentage of CHAMPUS patients who either have longer lengths of stay or require substantial amounts of inpatient care.

As was previously stated, it was Congress' intent for CHAMPUS to provide hospice care in the manner and under the conditions provided in section 1861(dd) of the Social Security Act (42 U.S.C. 1395x(dd)). Paragraph (2)(A)(iii) of this section requires assurance that the aggregate number of inpatient days does not exceed 20 percent of the aggregate number of days during the cap period. The only practical way of assuring this requirement is to incorporate it as part of the overall reimbursement methodology.

The aggregate limitations also lend themselves to the basic hospice philosophy of emphasizing home care over institutional care. The cap and inpatient limitations provide a financial incentive for home care delivery under the hospice all-inclusive prospective payment system. Elimination of such incentives might inadvertently result in overutilization of inpatient care (both respite and general inpatient care).

There could also be the assumption that since CHAMPUS beneficiaries constitute a younger population, their hospice care would be more conducive to a non-institutional setting (home health care setting) than the traditional Medicare population. Factors such as patient mobility and availability of family/care-givers would facilitate treatment in the home setting, thus reducing total expenditures and inpatient days for CHAMPUS beneficiaries.

Although the commenter's assumption that the vast majority of individual hospices will service only a very small number of CHAMPUS beneficiaries may be valid, there may be

those with significant volumes due to the concentration of military personnel in select geographic locations. These programs may provide care for the vast majority of CHAMPUS beneficiaries electing hospice care.

Comment 2. As part of the previous comment, it was recommended that the proposed CHAMPUS regulation, section 199.14, paragraph (g)(5)(D)(ii), be modified to make it clear that inpatient days in excess of the 80-20 rule be paid as routine home care days when calculating the amount refunded to CHAMPUS.

Procedural guidelines have been incorporated under section 199.14, paragraph (g)(4) describing the calculation of amounts in excess of the inpatient limitation which must be refunded to CHAMPUS. Paragraph (g)(4)(i)(C) of this section specifies that the actual inpatient days in excess of the limitation (20 percent of the aggregate inpatient days) will be paid at the routine home rate when calculating the amount refunded to CHAMPUS.

Comment 3. One commentor felt that CHAMPUS should not require hospice programs to collect copayments for outpatient drugs/biologicals and respite care since their collection was optional under Medicare and would impose an undue administration burden on those hospice programs which do not currently have a billing system in place for copayments.

Section 199.14, paragraph (g)(8) has been revised to make the collection of cost-shares of outpatient drugs/biologicals and respite care option under CHAMPUS.

Comment 4. Several commentors questioned the accuracy of the calculations in Table IV of the Supplementary Information section of the rule.

There was a transposition error in the example. The adjusted wage component of \$58.91 calculated in the first line of the table should have been added to the

nonwage component of \$39.50 to arrive at the adjusted rate of \$98.41. The adjusted rate should then have been divided by .95 to figure the rate for inpatient respite care including the coinsurance (\$103.59) and multiplied by .05 to arrive at a cost-share of \$5.18.

Comment 5. Several commenters felt that the combining of core service and 24-hour availability requirements caused confusion and led to the interpretation that drugs and biologicals, as non-core service, did not have to be routinely available on a 24-hour basis.

The core service and 24-hour availability requirements have been separated in order to alleviate the apparent confusion over drugs and biologicals. Refer to section 199.4 paragraphs (e)(19)(ii) through (iv) for revisions.

Comment 6. One commenter pointed out the draft CHAMPUS regulatory language does not say exactly what the Medicare regulations do concerning core services, substantially all of which must be routinely provided by employees of the hospice, and those services the hospice must make routinely available on a 24-hour basis. The commenter felt that these subtle distinctions/differences might cause confusion and differing interpretations.

Section 199.4, paragraphs (e)(19)(ii) and (iv) have been revised to reflect current Medicare language regarding core service and 24-hour availability requirements.

Comment 7. Several commentors indicated that section 199.4, paragraphs (e)(19)(iv) and (v)(B)(1) of the proposed rule did not say that the benefit periods may be elected separately at different times as specified in the Medicare hospice regulations. It was recommended that language be added to the referenced sections to clarify that breaks between benefit periods will also be allowed under CHAMPUS.

Section 199.4, paragraph (e)(19)(vi)(B)(1) has been revised to indicate that periods of care may be elected separately at different times.

Comment 8. One commenter expressed concern that the preamble language, as well as the proposed regulatory language, left uncertainty regarding whether OCHAMPUS will adopt future changes to the Medicare hospice benefit for its own CHAMPUS benefit so that the two benefits remain nearly identical. It was felt that a divergence in standards between the two programs could cause confusion and adversely affect a hospice's ability to serve CHAMPUS patients.

It is OCHAMPUS' intent to maintain a hospice benefit similar to, if not

identical to, that of Medicare. This includes the adoption of all future changes in the Medicare hospice conditions of participation.

Comment 9. One commenter felt that it was important that OCHAMPUS confirm that it intends to use the most current Medicare rates to reimburse hospices for services provided to CHAMPUS beneficiaries and to adopt changes in the Medicare reimbursement methodology as they occur; e.g., Medicare's adoption of an updated, more accurate wage index. The commenter recommended that regulatory language be added to section 199.14, paragraph (g) confirming CHAMPUS' intent to adopt future changes in the Medicare reimbursement methodology.

It is CHAMPUS' intent to use the most current Medicare rates to reimburse hospices for services to CHAMPUS beneficiaries and to adopt all changes to the Medicare reimbursement methodology as they occur. Regulatory language has been added to section 199.14 confirming CHAMPUS' intention of adopting future changes in the Medicare reimbursement methodology (refer to section 199.14, paragraph (g)(2)).

Comment 10. Several commentors felt there was an inconsistency between the preamble and proposed regulatory language regarding the patient's initial certification. It was pointed out that while section 199.4, paragraph (e)(19)(v)(A) requires the patient's initial certification to be provided in writing by the patient's attending physician (if there is one) and the hospice medical director or a physician member of the hospice interdisciplinary group, the preamble indicated that written certification must be provided in writing by the attending physician and/or the hospice medical director or a physician member of the hospice interdisciplinary group. The commenter felt that the use of "and/or" incorrectly suggested that either the attending physician or the medical director's certification is sufficient for the initial certification.

The patient's initial 90-day certification must be provided in writing by both the patient's attending physician (if there is one) and the hospice medical director or physician member of the hospice interdisciplinary group. For subsequent periods the only requirement is certification by the medical director of the hospice or the physician member of the hospice interdisciplinary group.

Comment 11. One commenter recommended that the definition of hospice care at § 199.2, paragraph (b)

and at § 199.4, paragraph (e)(19) be amended to add "palliative care" to the sentence: "This type of care emphasizes [palliative care] and supportive service * * *."

The recommendation has been adopted and incorporated into the final rule.

Comment 12. Several commentors recommended that the term "nursing home" be changed to Medicaid-certified nursing facility in § 199.4, paragraph (e)(19)(i)(H).

The commentors' recommendation was adopted and incorporated into the final rule.

Comment 13. One commenter felt that a cross-reference to the Medicare home health agency conditions of participation, 42 CFR 484.36, would be helpful in defining the term "qualified" aides in § 199.4, paragraph (e)(19)(i)(E).

A cross-reference has been provided in a note following § 199.4, paragraph (e)(19)(i)(E) which will help in defining the term "qualified" home health aide.

Comment 14. One commenter felt that the last sentence in proposed § 199.4, paragraph (e)(19)(i)(F) was not necessary and would only cause confusion since each of the covered services enumerated in § 199.4, paragraphs (e)(19)(i)(A)–(H) are covered only if the service or item is included in the patient's plan of care.

The last sentence has been deleted from the final rule.

Comment 15. One commenter pointed out that Medicare policy defines "terminal" as six months or less if the disease runs its normal course.

The definition of "terminal" has been expanded wherever cited in the final regulation.

Comment 16. One commenter recommended that the requirement that the hospice must maintain professional management of the patient at all times be expanded to include "and in all settings."

The recommendation was adopted and incorporated into the final rule.

Comment 17. One commenter wanted clarification regarding the word "participating" in § 199.4, paragraph (e)(19)(i)(H).

A hospice program must be Medicare approved (i.e., a state agency must certify to the Department of Health and Human Services that a hospice meets the conditions of participation established in 42 CFR Part 418—

Hospice Care) in order to participate in the CHAMPUS program. The hospice will only be allowed to participate (enter into a participation agreement with CHAMPUS) if there is proof that it is a Medicare approved facility. Respite care is the only type of inpatient care that may be provided in a nursing

facility (formally known as an intermediate care facility—ICF). A nursing facility must be certified by a state Medicaid agency as well as meet the conditions for participation under 42 CFR 418.100 in order to participate in CHAMPUS.

Comment 18. One commentor pointed out that CHAMPUS' requirement that short-term inpatient care be provided in Medicare participating facilities precludes/prohibits the coverage of inpatient care in VA hospitals.

Hospice care will not be allowed in VA hospitals under the provisions of this rule.

Comment 19. One commenter wanted to know if CHAMPUS intended to use the Health Care Financing Administration's (HCFA) wage index adjustments for hospice reimbursement.

Yes, CHAMPUS intends to use HCFA's wage index adjustments for hospice reimbursement. These wage indices have been in use since the inception of the Medicare hospice benefit in 1983, and are different than those used in calculation of CHAMPUS DRGs and mental health per diems.

Comment 20. Several editorial comments were received from one of CHAMPUS' administrative agencies.

All of these comments were adopted and incorporated into the final rule.

Summary of Regulatory Modifications

The following modifications were made as a result of suggestions received during the public comment period:

- (1) The core services and 24-hour availability requirements were separated out as distinct provisions;
- (2) the collection of cost-shares by individual hospices for outpatient drugs/biologicals and respite care was made optional under CHAMPUS;
- (3) regulatory language was added confirming CHAMPUS's intention of adopting future changes in Medicare reimbursement methodology;
- (4) procedures were added for changes in designation of hospice programs;
- (5) exceptions were provided for waiver of payment of other basic program services related to treatment of terminal illness;
- (6) a note was added regarding the information required on the treatment plan; and
- (7) payment provisions were modified to allow 100 percent payment of CHAMPUS allowed charges for hospice physicians providing direct patient care.

Provider Notification

The CHAMPUS contractors will be sending out letters along with CHAMPUS participation agreements, on a one time basis, to all hospice programs certified to participate in Medicare

within their jurisdictional areas. The letters will provide information regarding the new hospice benefit and encourage participation under CHAMPUS. A hospice program will be certified based solely on its appearance on a current Medicare listing. No additional information will be required except for the signed CHAMPUS participation agreement which accompanied the notification letter. Thereafter, hospice programs will have to contact the CHAMPUS contractor responsible for claims processing within their geographical area for certification under CHAMPUS. The hospice will have to provide documentation that it is certified to participate in Medicare (i.e., it meets all Medicare conditions of participation (42 CFR Part 418) relative to CHAMPUS beneficiaries) and that it and its employees are licensed in accordance with applicable Federal, State and local laws and regulations. The hospice will be provided with a participation agreement for signature if the above requirements are met. An agreement with a hospice is not time-limited and has no fixed expiration date. The agreement remains in effect until such time as there is a voluntary or involuntary termination.

Regulatory Procedures

Executive Order 12866 requires that a regulatory impact analysis be performed on any significant action. A "significant action" is defined as one which would result in an annual effect on the national economy of \$100 million or more, or which would have other substantial impacts.

The Regulatory Flexibility Act (RFA) requires that each federal agency prepare, and make available for public comment, a regulatory flexibility analysis when the agency issues a regulation which would have a significant impact on a substantial number of small entities.

This final rule is not a major rule under Executive Order 12866. The changes set forth in this final rule are minor revisions to existing regulation. The changes made in this final rule involve an expansion of CHAMPUS benefits. In addition, this final rule will have minor impact and will not significantly affect a substantial number of small entities. In light of the above, no regulatory impact analysis is required.

We certify that this final rule has been reviewed under the provisions of the October 23, 1991, Executive Order on Civil Justice Reform. This final rule meets all applicable standards provided in that executive order.

This rule does impose minimal information collection requirements to include the following: (1) Total number of CHAMPUS inpatient hospice days; (2) total number of CHAMPUS hospice days (both inpatient and home care); (3) total number of CHAMPUS beneficiaries electing hospice care; (4) total reimbursement for CHAMPUS inpatient care; and (5) total reimbursement for all CHAMPUS hospice care (both inpatient and home care).

The fact that all CHAMPUS-approved hospice programs are subject to Medicare reporting requirements (i.e., they must be Medicare certified in order to receive CHAMPUS reimbursement), will tend to minimize the administrative burden imposed by this rule. The hospice will already have an established data collection system in place for developing these annual reports. Overall, resource allocation (administrative time) will be minimal since the number of CHAMPUS hospice beneficiaries would be disproportionately low compared to the number of Medicare patients. In other words, since the facility already has to collect, arrange, and submit the data on a majority of its patients, the administrative costs and/or burden of reporting CHAMPUS hospice patients would be minimal. The hospice would have to expand only the data collection parameters (data on CHAMPUS beneficiaries) in order to meet the requirements under this rule.

The rule represents an expansion of benefits under the CHAMPUS program, resulting in certification of a new provider category (hospice). Although hospice programs are accustomed to the proposed reporting requirements and would not view this as an administrative intrusion, the final rule has been prepared for review by the Executive Office of Management and Budget under authority of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501–3520).

List of Subjects in 32 CFR Part 199

Claims, handicapped, health insurance, and military personnel.

Accordingly, 32 CFR part 199, is amended as follows:

PART 199—CIVILIAN HEALTH AND MEDICAL PROGRAM OF THE UNIFORMED SERVICES (CHAMPUS)

1. The authority citation for Part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. 1079, 1086.

2. Section 199.2(b) is amended by adding a definition for "hospice care"

and "respite care" in alphabetical order to read as follows:

§ 199.2 Definitions.

* * * * *

(b) * * *

Hospice care. Hospice care is a program which provides an integrated set of services and supplies designed to care for the terminally ill. This type of care emphasizes palliative care and supportive services, such as pain control and home care, rather than cure-oriented services provided in institutions that are otherwise the primary focus under CHAMPUS. The benefit provides coverage for a humane and sensible approach to care during the last days of life for some terminally ill patients.

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Respite care. Respite care is short-term care for a patient in order to provide rest and change for those who have been caring for the patient at home, usually the patient's family.

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3. Section 199.4 is amended by adding new paragraph (e)(19) to read as follows:

§ 199.4 Basic program benefits.

* * * * *

(e) * * *

(19) *Hospice care.* Hospice care is a program which provides an integrated set of services and supplies designed to care for the terminally ill. This type of care emphasizes palliative care and supportive services, such as pain control and home care, rather than cure-oriented services provided in institutions that are otherwise the primary focus under CHAMPUS. The benefit provides coverage for a humane and sensible approach to care during the last days of life for some terminally ill patients.

(i) *Benefit coverage.* CHAMPUS beneficiaries who are terminally ill (that is, a life expectancy of six months or less if the disease runs its normal course) will be eligible for the following services and supplies in lieu of most other CHAMPUS benefits:

- (A) Physician services.
- (B) Nursing care provided by or under the supervision of a registered professional nurse.
- (C) Medical social services provided by a social worker who has at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education, and who is working under the direction of a physician. Medical social services include, but are not limited to the following:

(1) Assessment of social and emotional factors related to the beneficiary's illness, need for care, response to treatment, and adjustment to care.

(2) Assessment of the relationship of the beneficiary's medical and nursing requirements to the individual's home situation, financial resources, and availability of community resources.

(3) Appropriate action to obtain available community resources to assist in resolving the beneficiary's problem.

(4) Counseling services that are required by the beneficiary.

(D) Counseling services provided to the terminally ill individual and the family member or other persons caring for the individual at home. Counseling, including dietary counseling, may be provided both for the purpose of training the individual's family or other care-giver to provide care, and for the purpose of helping the individual and those caring for him or her to adjust to the individual's approaching death. Bereavement counseling, which consists of counseling services provided to the individual's family after the individual's death, is a required hospice service but it is not reimbursable.

(E) Home health aide services furnished by qualified aides and homemaker services. Home health aides may provide personal care services. Aides also may perform household services to maintain a safe and sanitary environment in areas of the home used by the patient. Examples of such services are changing the bed or light cleaning and laundering essential to the comfort and cleanliness of the patient. Aide services must be provided under the general supervision of a registered nurse. Homemaker services may include assistance in personal care, maintenance of a safe and healthy environment, and services to enable the individual to carry out the plan of care. Qualifications for home health aides can be found in 42 CFR 484.36.

(F) Medical appliances and supplies, including drugs and biologicals. Only drugs that are used primarily for the relief of pain and symptom control related to the individual's terminal illness are covered. Appliances may include covered durable medical equipment, as well as other self-help and personal comfort items related to the palliation or management of the patient's condition while he or she is under hospice care. Equipment is provided by the hospice for use in the beneficiary's home while he or she is under hospice care. Medical supplies include those that are part of the written plan of care. Medical appliances and

supplies are included within the hospice all-inclusive rates.

(G) Physical therapy, occupational therapy and speech-language pathology services provided for purposes of symptom control or to enable the individual to maintain activities of daily living and basic functional skills.

(H) Short-term inpatient care provided in a Medicare participating hospice inpatient unit, or a Medicare participating hospital, skilled nursing facility (SNF) or, in the case of respite care, a Medicaid-certified nursing facility that additionally meets the special hospice standards regarding staffing and patient areas. Services provided in an inpatient setting must conform to the written plan of care. Inpatient care may be required for procedures necessary for pain control or acute or chronic symptom management. Inpatient care may also be furnished to provide respite for the individual's family or other persons caring for the individual at home. Respite care is the only type of inpatient care that may be provided in a Medicaid-certified nursing facility. The limitations on custodial care and personal comfort items applicable to other CHAMPUS services are not applicable to hospice care.

(ii) *Core services.* The hospice must ensure that substantially all core services are routinely provided directly by hospice employees; i.e., physician services, nursing care, medical social services, and counseling for individuals and care givers. Refer to paragraphs (e)(19)(i)(A), (e)(19)(i)(B), (e)(19)(i)(C), and (e)(19)(i)(D) of this section.

(iii) *Non-core services.* While non-core services (i.e., home health aide services, medical appliances and supplies, drugs and biologicals, physical therapy, occupational therapy, speech-language pathology and short-term inpatient care) may be provided under arrangements with other agencies or organizations, the hospice must maintain professional management of the patient at all times and in all settings. Refer to paragraphs (e)(19)(i)(E), (e)(19)(i)(F), (e)(19)(i)(G), and (e)(19)(i)(H) of this section.

(iv) *Availability of services.* The hospice must make nursing services, physician services, and drugs and biologicals routinely available on a 24-hour basis. All other covered services must be made available on a 24-hour basis to the extent necessary to meet the needs of individuals for care that is reasonable and necessary for the palliation and management of the terminal illness and related condition. These services must be provided in a

manner consistent with accepted standards of practice.

(v) *Periods of care.* Hospice care is divided into distinct periods/episodes of care. The terminally ill beneficiary may elect to receive hospice benefits for an initial period of 90 days, a subsequent period of 90 days, a second subsequent period of 30 days, and a final period of unlimited duration.

(vi) *Conditions for coverage.* The CHAMPUS beneficiary must meet the following conditions/criteria in order to be eligible for the hospice benefits and services referenced in paragraph (e)(19)(i) of this section.

(A) There must be written certification in the medical record that the CHAMPUS beneficiary is terminally ill with a life expectancy of six months or less if the terminal illness runs its normal course.

(1) *Timing of certification.* The hospice must obtain written certification of terminal illness for each of the election periods described in paragraph (e)(19)(vi)(B) of this section, even if a single election continues in effect for two, three or four periods.

(i) *Basic requirement.* Except as provided in paragraph (e)(19)(vi)(A)(1)(ii) of this section the hospice must obtain the written certification no later than two calendar days after the period begins.

(ii) *Exception.* For the initial 90-day period, if the hospice cannot obtain the written certifications within two calendar days, it must obtain oral certifications within two calendar days, and written certifications no later than eight calendar days after the period begins.

(2) *Sources of certification.* Physician certification is required for both initial and subsequent election periods.

(i) For the initial 90-day period, the hospice must obtain written certification statements (and oral certification statements if required under paragraph (e)(19)(vi)(A)(i)(ii) of this section) from:

(A) The individual's attending physician if the individual has an attending physician; and

(B) The medical director of the hospice or the physician member of the hospice interdisciplinary group.

(ii) For subsequent periods, the only requirement is certification by one of the physicians listed in paragraph (e)(19)(vi)(A)(2)(i)(B) of this section.

(B) The terminally ill beneficiary must elect to receive hospice care for each specified period of time; i.e., the two 90-day periods, a subsequent 30-day period, and a final period of unlimited duration. If the individual is found to be mentally incompetent, his or her

representative may file the election statement. Representative means an individual who has been authorized under State law to terminate medical care or to elect or revoke the election of hospice care on behalf of a terminally ill individual who is found to be mentally incompetent.

(1) The episodes of care must be used consecutively; i.e., the two 90-day periods first, then the 30-day period, followed by the final period. The periods of care may be elected separately at different times.

(2) The initial election will continue through subsequent election periods without a break in care as long as the individual remains in the care of the hospice and does not revoke the election.

(3) The effective date of the election may begin on the first day of hospice care or any subsequent day of care, but the effective date cannot be made prior to the date that the election was made.

(4) The beneficiary or representative may revoke a hospice election at any time, but in doing so, the remaining days of that particular election period are forfeited and standard CHAMPUS coverage resumes. To revoke the hospice benefit, the beneficiary or representative must file a signed statement of revocation with the hospice. The statement must provide the date that the revocation is to be effective. An individual or representative may not designate an effective date earlier than the date that the revocation is made.

(5) If an election of hospice benefits has been revoked, the individual, or his or her representative may at any time file a hospice election for any period of time still available to the individual, in accordance with § 199.4(e)(19)(vi)(B).

(6) A CHAMPUS beneficiary may change, once in each election period, the designation of the particular hospice from which he or she elects to receive hospice care. To change the designation of hospice programs the individual or representative must file, with the hospice from which care has been received and with the newly designated hospice, a statement that includes the following information:

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

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

(7) Each hospice will design and print its own election statement to include the following information:

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

(ii) The individual's or representative's acknowledgment that he or she has been given a full understanding of the palliative rather than curative nature of hospice care, as it relates to the individual's terminal illness.

(iii) The individual's or representative's acknowledgment that he or she understands that certain other CHAMPUS services are waived by the election.

(iv) The effective date of the election.

(v) The signature of the individual or representative, and the date signed.

(8) The hospice must notify the CHAMPUS contractor of the initiation, change or revocation of any election.

(c) The beneficiary must waive all rights to other CHAMPUS payments for the duration of the election period for:

(1) Care provided by any hospice program other than the elected hospice unless provided under arrangements made by the elected hospice; and

(2) Other CHAMPUS basic program services/benefits related to the treatment of the terminal illness for which hospice care was elected, or to a related condition, or that are equivalent to hospice care, except for services provided by:

(i) the designated hospice;

(ii) another hospice under arrangement made by the designated hospice; or

(iii) an attending physician who is not employed by or under contract with the hospice program.

(3) Basic CHAMPUS coverage will be reinstated upon revocation of the hospice election.

(D) A written plan of care must be established by a member of the basic interdisciplinary group assessing the patient's needs. This group must have at least one physician, one registered professional nurse, one social worker, and one pastoral or other counselor.

(1) In establishing the initial plan of care the member of the basic interdisciplinary group who assesses the patient's needs must meet or call at least one other group member before writing the initial plan of care.

(2) At least one of the persons involved in developing the initial plan must be a nurse or physician.

(3) The plan must be established on the same day as the assessment if the day of assessment is to be a covered day of hospice care.

(4) The other two members of the basic interdisciplinary group—the attending physician and the medical director or physician designee—must review the initial plan of care and provide their input to the process of establishing the plan of care within two

calendar days following the day of assessment. A meeting of group members is not required within this 2-day period. Input may be provided by telephone.

(5) Hospice services must be consistent with the plan of care for coverage to be extended.

(6) The plan must be reviewed and updated, at intervals specified in the plan, by the attending physician, medical director or physician designee and interdisciplinary group. These reviews must be documented in the medical records.

(7) The hospice must designate a registered nurse to coordinate the implementation of the plan of care for each patient.

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

(E) Complete medical records and all supporting documentation must be submitted to the CHAMPUS contractor within 30 days of the date of its request. If records are not received within the designated time frame, authorization of the hospice benefit will be denied and any prior payments made will be recouped. A denial issued for this reason is not an initial determination under section 199.10, and is not appealable.

(vii) *Appeal rights under hospice benefit.* A beneficiary or provider is entitled to appeal rights for cases involving a denial of benefits in accordance with the provisions of this part and part 199.10.

* * * * *

4. Section 199.6 is amended by adding new paragraph (b)(4)(xiii) to read as follows:

§ 199.6 Authorized providers.

* * * * *

(b) * * *

(4) * * *

(xiii) *Hospice programs.* Hospice programs must be Medicare approved and meet all Medicare conditions of participation (42 CFR Part 418) in relation to CHAMPUS patients in order to receive payment under the CHAMPUS program. A hospice program may be found to be out of compliance with a particular Medicare condition of participation and still participate in the CHAMPUS as long as the hospice is allowed continued participation in Medicare while the condition of noncompliance is being corrected. The hospice program can be either a public

agency or private organization (or a subdivision thereof) which:

(A) Is primarily engaged in providing the care and services described under § 199.4(e)(19) and makes such services available on a 24-hour basis.

(B) Provides bereavement counseling for the immediate family or terminally ill individuals.

(C) Provides for such care and services in individuals' homes, on an outpatient basis, and on a short-term inpatient basis, directly or under arrangements made by the hospice program, except that the agency or organization must:

(1) Ensure that substantially all the core services are routinely provided directly by hospice employees.

(2) Maintain professional management responsibility for all services which are not directly furnished to the patient, regardless of the location or facility in which the services are rendered.

(3) Provide assurances that the aggregate number of days of inpatient care provided in any 12-month period does not exceed 20 percent of the aggregate number of days of hospice care during the same period.

(4) Have an interdisciplinary group composed of the following personnel who provide the care and services described under § 199.4(e)(19) and who establish the policies governing the provision of such care/services:

- (i) A physician;
- (ii) A registered professional nurse;
- (iii) A social worker; and
- (iv) A pastoral or other counselor.

(5) Maintain central clinical records on all patients.

(6) Utilize volunteers.

(7) The hospice and all hospice employees must be licensed in accordance with applicable Federal, State and local laws and regulations.

(8) The hospice must enter into an agreement with CHAMPUS in order to be qualified to participate and to be eligible for payment under the program. In this agreement the hospice and CHAMPUS agree that the hospice will:

(i) Not charge the beneficiary or any other person for items or services for which the beneficiary is entitled to have payment made under the CHAMPUS hospice benefit.

(ii) Be allowed to charge the beneficiary for items or services requested by the beneficiary in addition to those that are covered under the CHAMPUS hospice benefit.

(9) Meet such other requirements as the Secretary of Defense may find necessary in the interest of the health and safety of the individuals who are

provided care and services by such agency or organization.

* * * * *

5. Section 199.14 is amended by redesignating paragraphs (g), (h), (i), (j), and (k) as (h), (i), (j), (k), and (l), adding new paragraph (g).

§ 199.14 Provider reimbursement methods.

* * * * *

(g) *Reimbursement of hospice programs.* Hospice care will be reimbursed at one of four predetermined national CHAMPUS rates based on the type and intensity of services furnished to the beneficiary. A single rate is applicable for each day of care except for continuous home care where payment is based on the number of hours of care furnished during a 24-hour period. These rates will be adjusted for regional differences in wages using wage indices for hospice care.

(1) *National hospice rates.* CHAMPUS will use the national hospice rates for reimbursement of each of the following levels of care provided by or under arrangement with a CHAMPUS approved hospice program:

(i) *Routine home care.* The hospice will be paid the routine home care rate for each day the patient is at home, under the care of the hospice, and not receiving continuous home care. This rate is paid without regard to the volume or intensity of routine home care services provided on any given day.

(ii) *Continuous home care.* The hospice will be paid the continuous home care rate when continuous home care is provided. The continuous home care rate is divided by 24 hours in order to arrive at an hourly rate.

(A) A minimum of 8 hours of care must be provided within a 24-hour day starting and ending at midnight.

(B) More than half of the total actual hours being billed for each 24-hour period must be provided by either a registered or licensed practical nurse.

(C) Homemaker and home health aide services may be provided to supplement the nursing care to enable the beneficiary to remain at home.

(D) For every hour or part of an hour of continuous care furnished, the hourly rate will be reimbursed to the hospice up to 24 hours a day.

(iii) *Inpatient respite care.* The hospice will be paid at the inpatient respite care rate for each day on which the beneficiary is in an approved inpatient facility and is receiving respite care.

(A) Payment for respite care may be made for a maximum of 5 days at a time, including the date of admission but not counting the date of discharge. The

necessity and frequency of respite care will be determined by the hospice interdisciplinary group with input from the patient's attending physician and the hospice's medical director.

(B) Payment for the sixth and any subsequent days is to be made at the routine home care rate.

(iv) *General inpatient care.* Payment at the inpatient rate will be made when general inpatient care is provided for pain control or acute or chronic symptom management which cannot be managed in other settings. None of the other fixed payment rates (i.e., routine home care) will be applicable for a day on which the patient receives general inpatient care except on the date of discharge.

(v) *Date of discharge.* For the day of discharge from an inpatient unit, the appropriate home care rate is to be paid unless the patient dies as an inpatient. When the patient is discharged deceased, the inpatient rate (general or respite) is to be paid for the discharge date.

(2) *Use of Medicare rates.* CHAMPUS will use the most current Medicare rates to reimburse hospice programs for services provided to CHAMPUS beneficiaries. It is CHAMPUS' intent to adopt changes in the Medicare reimbursement methodology as they occur; e.g., Medicare's adoption of an updated, more accurate wage index.

(3) *Physician reimbursement.* Payment is dependent on the physician's relationship with both the beneficiary and the hospice program.

(i) *Physicians employed by, or contracted with, the hospice.*

(A) Administrative and supervisory activities (i.e., establishment, review and updating of plans of care, supervising care and services, and establishing governing policies) are included in the adjusted national payment rate.

(B) Direct patient care services are paid in addition to the adjusted national payment rate.

(1) Physician services will be reimbursed an amount equivalent to 100 percent of the CHAMPUS' allowable charge; i.e., there will be no cost-sharing and/or deductibles for hospice physician services.

(2) Physician payments will be counted toward the hospice cap limitation.

(ii) *Independent attending physician.* Patient care services rendered by an independent attending physician (a physician who is not considered employed by or under contract with the hospice) are not part of the hospice benefit.

(A) Attending physician may bill in his/her own right.

(B) Services will be subject to the appropriate allowable charge methodology.

(C) Reimbursement is not counted toward the hospice cap limitation.

(D) Services provided by an independent attending physician must be coordinated with any direct care services provided by hospice physicians.

(E) The hospice must notify the CHAMPUS contractor of the name of the physician whenever the attending physician is not a hospice employee.

(iii) *Voluntary physician services.* No payment will be allowed for physician services furnished voluntarily (both physicians employed by, and under contract with, the hospice and independent attending physicians). Physicians may not discriminate against CHAMPUS beneficiaries; e.g., designate all services rendered to non-CHAMPUS patients as volunteer and at the same time bill for CHAMPUS patients.

(4) *Unrelated medical treatment.* Any covered CHAMPUS services not related to the treatment of the terminal condition for which hospice care was elected will be paid in accordance with standard reimbursement methodologies; i.e., payment for these services will be subject to standard deductible and cost-sharing provisions under the CHAMPUS. A determination must be made whether or not services provided are related to the individual's terminal illness. Many illnesses may occur when an individual is terminally ill which are brought on by the underlying condition of the ill patient. For example, it is not unusual for a terminally ill patient to develop pneumonia or some other illness as a result of his or her weakened condition. Similarly, the setting of bones after fractures occur in a bone cancer patient would be treatment of a related condition. Thus, if the treatment or control of an upper respiratory tract infection is due to the weakened state of the terminal patient, it will be considered a related condition, and as such, will be included in the hospice daily rates.

(5) *Cap amount.* Each CHAMPUS-approved hospice program will be subject to a cap on aggregate CHAMPUS payments from November 1 through October 31 of each year, hereafter known as "the cap period."

(i) The cap amount will be adjusted annually by the percent of increase or decrease in the medical expenditure category of the Consumer Price Index for all urban consumers (CPI-U).

(ii) The aggregate cap amount (i.e., the statutory cap amount times the number

of CHAMPUS beneficiaries electing hospice care during the cap period) will be compared with total actual CHAMPUS payments made during the same cap period.

(iii) Payments in excess of the cap amount must be refunded by the hospice program. The adjusted cap amount will be obtained from the Health Care Financing Administration (HCFA) prior to the end of each cap period.

(iv) Calculation of the cap amount for a hospice which has not participated in the program for an entire cap year (November 1 through October 31) will be based on a period of at least 12 months but no more than 23 months. For example, the first cap period for a hospice entering the program on October 1, 1994, would run from October 1, 1994 through October 31, 1995. Similarly, the first cap period for hospice providers entering the program after November 1, 1993 but before November 1, 1994 would end October 31, 1995.

(6) *Inpatient limitation.* During the 12-month period beginning November 1 of each year and ending October 31, the aggregate number of inpatient days, both for general inpatient care and respite care, may not exceed 20 percent of the aggregate total number of days of hospice care provided to all CHAMPUS beneficiaries during the same period.

(i) If the number of days of inpatient care furnished to CHAMPUS beneficiaries exceeds 20 percent of the total days of hospice care to CHAMPUS beneficiaries, the total payment for inpatient care is determined follows:

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

(B) Multiply this ratio by the total reimbursement for inpatient care made by the CHAMPUS contractor.

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

(D) Add the amounts calculated in paragraphs (g)(6)(i) (B) and (C) of this section.

(ii) Compare the total payment for inpatient care calculated in paragraph (g)(6)(i)(D) of this section to actual payments made to the hospice for inpatient care during the cap period.

(iii) Payments in excess of the inpatient limitation must be refunded by the hospice program.

(7) *Hospice reporting responsibilities.* The hospice is responsible for reporting the following data within 30 days after the end of the cap period:

(i) Total reimbursement received and receivable for services furnished CHAMPUS beneficiaries during the cap period, including physician's services not of an administrative or general supervisory nature.

(ii) Total reimbursement received and receivable for general inpatient care and inpatient respite care furnished to CHAMPUS beneficiaries during the cap period.

(iii) Total number of inpatient days furnished to CHAMPUS hospice patients (both general inpatient and inpatient respite days) during the cap period.

(iv) Total number of CHAMPUS hospice days (both inpatient and home care) during the cap period.

(v) Total number of beneficiaries electing hospice care. The following rules must be adhered to by the hospice in determining the number of CHAMPUS beneficiaries who have elected hospice care during the period:

(A) The beneficiary must not have been counted previously in either another hospice's cap or another reporting year.

(B) The beneficiary must file an initial election statement during the period beginning September 28 of the previous cap year through September 27 of the current cap year in order to be counted as an electing CHAMPUS beneficiary during the current cap year.

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

(D) There will be proportional application of the cap amount when a beneficiary elects to receive hospice benefits from two or more different CHAMPUS-certified hospices. A calculation must be made to determine the percentage of the patient's length of stay in each hospice relative to the total length of hospice stay.

(8) *Reconsideration of cap amount and inpatient limit.* A hospice dissatisfied with the contractor's calculation and application of its cap amount and/or inpatient limitation may request and obtain a contractor review if the amount of program reimbursement in controversy—with respect to matters which the hospice has a right to review—is at least \$1000. The administrative review by the contractor of the calculation and application of the cap amount and inpatient limitation is the only administrative review available. These calculations are not subject to the appeal procedures set

forth in § 199.10. The methods and standards for calculation of the hospice payment rates established by CHAMPUS, as well as questions as to the validity of the applicable law, regulations or CHAMPUS decisions, are not subject to administrative review, including the appeal procedures of § 199.10.

(9) *Beneficiary cost-sharing.* There are no deductibles under the CHAMPUS hospice benefit. CHAMPUS pays the full cost of all covered services for the terminal illness, except for small cost-share amounts which *may be* collected by the individual hospice for outpatient drugs and biologicals and inpatient respite care.

(i) The patient is responsible for 5 percent of the cost of outpatient drugs or \$5 toward each prescription, whichever is less. Additionally, the cost of prescription drugs (drugs or biologicals) may not exceed that which a prudent buyer would pay in similar circumstances; that is, a buyer who refuses to pay more than the going price for an item or service and also seeks to economize by minimizing costs.

(ii) For inpatient respite care, the cost-share for each respite care day is equal to 5 percent of the amount CHAMPUS has estimated to be the cost of respite care, after adjusting the national rate for local wage differences.

(iii) The amount of the individual cost-share liability for respite care during a hospice cost-share period may not exceed the Medicare inpatient hospital deductible applicable for the year in which the hospice cost-share period began. The individual hospice cost-share period begins on the first day an election is in effect for the beneficiary and ends with the close of the first period of 14 consecutive days on each of which an election is not in effect for the beneficiary.

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Dated: January 25, 1995.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

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DEPARTMENT OF THE INTERIOR

National Park Service

36 CFR Part 7

RIN 1024-AB10

Everglades National Park Special Regulations; Correction

AGENCY: National Park Service, Interior.

ACTION: Correction to final regulations.

SUMMARY: This document contains corrections to the final regulations which were published Tuesday, November 15, 1994. The regulations related to fishing and boating activities within Everglades National Park.

EFFECTIVE DATE: December 15, 1994.

FOR FURTHER INFORMATION CONTACT: Superintendent, Everglades National Park, 40001 State Road 9336, Homestead, FL 33034. Telephone (305) 242-7730.

SUPPLEMENTARY INFORMATION:

Background

On November 15, 1994, the National Park Service (NPS) published in the **Federal Register** (59 FR 58781) a final rule changing the special regulations for Everglades National Park. The final rule completely revises the special regulations for the park. The rule achieves consistency with State fishing rules and allows the park to adopt State fishing regulations. It more closely regulates the activities of commercial guide fishing and redefines "commercial fishing" to include the taking of sponges and other non-edible marine life.

The final rule allows the NPS to take a more proactive role in its mission to protect and conserve natural and cultural resources and gives the Superintendent more specific authority to regulate fishing and boating. It prohibits the use of personal watercraft, closes accessible marine wilderness areas to the use of motorized vessels and allows for better management of wildlife habitat sites. The rule also deletes existing obsolete regulations from the Code of Federal Regulations pertaining to mining and commercial fishing.

Need for Correction

As published, the final rule contains two typographical errors which may prove to be misleading and are in need of correction.

Correction of Publication

Accordingly, the publication on November 15, 1994 (59 FR 58781) of the final regulation, rule document 94-