

Health Care Financing Administration**42 CFR Part 406**

[BPD-738-F]

RIN 0938-AG19

Medicare Program; Clarification of Resumption of Entitlement Rules for Medicare Patients With End-Stage Renal Disease (ESRD)

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

ACTION: Final rule.

SUMMARY: In this final rule, we clarify the terms of Medicare entitlement when an individual resumes a regular course of renal dialysis treatment or receives a kidney transplant after a previous course of treatment has been terminated (with or without a transplant) and add the same considerations for those who have a second transplant or begin dialysis after a previous transplant. We also respond to comments on a proposal to revise the definition of ESRD for the purpose of qualifying for Medicare.

These revisions are necessary so that beneficiaries, providers, suppliers, and other insurers can determine with certainty when Medicare coverage begins and ends. Beneficiaries rely on this information to make informed decisions whether or not to enroll or re-enroll in the Medicare Supplementary Medical Insurance Program (part B).

EFFECTIVE DATE: These regulations are effective on June 7, 1995.

FOR FURTHER INFORMATION CONTACT: Denis Garrison, (410) 966-5643.

SUPPLEMENTARY INFORMATION:**I. Background**

End-stage renal disease (ESRD) is a disease that results from the destruction of normal kidney tissues over a long period of time. The individual often does not experience any symptoms until the kidney has lost more than half of its function. The loss of kidney function in ESRD is usually irreversible and permanent.

Definition of ESRD

Section 226A of the Social Security Act (the Act) provides for Medicare coverage for certain individuals who are medically determined to have ESRD. Once an individual is medically determined to have ESRD, the Act specifies that one of two conditions must be met before entitlement begins. That is, the individual must begin a regular course of dialysis or receive a kidney transplant. The Act provides that entitlement begins with the third month after the month in which a regular

course of renal dialysis is initiated or, if earlier, with the month the transplant occurs.

The Act does not define ESRD. Our regulations, in § 406.13(b), define it as that stage of kidney impairment that appears irreversible and permanent and requires a regular course of dialysis or kidney transplantation to maintain life. (A parallel definition of ESRD also appears in § 405.2102 which defines ESRD as it relates to the conditions for coverage that must be met by suppliers furnishing ESRD care to Medicare beneficiaries.)

Resumption of Entitlement to ESRD Benefits

Paragraphs (c)(2) and (c)(3) of section 226A of the Act specify the conditions for beginning a new period of entitlement when a kidney transplant fails or a regular course of dialysis begins again. However, this section refers to those instances when entitlement has not yet ended and specifies that Part A (Hospital Insurance) entitlement "begins" (although it may not yet have ended) with the month when regular dialysis treatments begin again. The importance of "beginning" Part A entitlement again is that it offers the opportunity for those who previously refused Part B (Supplementary Medical Insurance) entitlement or allowed their Part B entitlement to lapse to enroll in Part B without waiting for the annual general enrollment period (January through March). Most kidney dialysis treatments are covered under Part B.

Proposed Rule

On January 6, 1994, we published a proposed rule, at 59 FR 714, which proposed a change in the definition of end-stage renal disease (ESRD) and a clarification regarding Medicare entitlement when an individual's regular course of renal dialysis treatment resumes after a previous course of treatment has been terminated (with or without a transplant). The proposal resulted from our concern that there may be a misunderstanding of the extent of kidney failure that constitutes ESRD for which the law grants Medicare entitlement. We were also concerned that our regulations on resumption of entitlement based on ESRD might be misinterpreted resulting in loss of benefits for some individuals. Further, for those individuals whose Part A entitlement had not yet ended, we believe that the intention is to re-enroll the individual in Part A with that month, without a new application.

Proposed definition—We were concerned that data revealed nearly 1

percent of newly entitled individuals terminated their course of dialysis with a return of kidney function. We believed that physicians' certifications leading to eligibility for the patients who terminated dialysis may have arisen from a misunderstanding of the extent of the kidney failure that is a predicate to Medicare entitlement. Consequently, we proposed to amend the definition of ESRD that appeared in § 406.13 to require that the condition be "evidenced by generally accepted diagnostic criteria and laboratory findings." We believed that this addition would make clear that an individual who receives dialysis does not necessarily have end-stage renal disease.

End of and Resumption of Entitlement—We proposed to treat the situation in which dialysis ends, then begins again within 12 months, or in which a second transplant is received within 36 months, as a *resumption* of entitlement. Accordingly, we proposed to delete from paragraph (f) of § 406.13 the reference to *continuation* of entitlement. We would revise paragraph (g), which specifies the conditions for resumption of entitlement, to include the situation where coverage resumes despite a previous course of treatment.

In our revision of § 406.13(g) we stated that entitlement would be resumed under any one of three conditions and we used the language we removed from paragraph (f). Under § 406.13(g)(1), a new period of entitlement would begin if an individual initiates a regular course of renal dialysis during the 12-month period after the previous course of dialysis ended, and he or she would be entitled to a new period of Part A benefits and, therefore, eligible to enroll in Part B effective with the month the regular course of dialysis is resumed.

The Act does not mention the beginning of a new period of entitlement when a second kidney transplant occurs during the 36-month period following the initial transplant, since there is never a waiting period for entitlement based on a transplant. However, we believe that, by analogy, the provisions for beginning a new period of entitlement in cases where a regular course of dialysis begins or recurs during the 36 months indicate that we should construe the law as requiring resumption of Part A entitlement and a new period of Part B enrollment in cases of re-transplantation that occur without the beneficiary's resuming (or initiating) dialysis treatments. We, therefore, proposed to revise § 406.13(g) to state that entitlement would begin when an individual initiates a new, regular

course of renal dialysis, or has a kidney transplant, during the 36-month period after an earlier kidney transplant, and that he or she would be entitled to resume Part A and be eligible to enroll in Part B effective with the month the regular course of dialysis begins or with the month the subsequent kidney transplant occurs.

We also proposed to make technical revisions to § 406.13(g) to clarify the other condition for resumption of entitlement. That is, entitlement is resumed if an individual initiates a regular course of renal dialysis more than 12 months after the previous regular course of dialysis ended or more than 36 months after the month of a kidney transplant, and the individual is eligible to enroll in Part A and Part B effective with the month in which the regular course of dialysis treatment is resumed. If he or she is otherwise eligible to Part A benefits under the conditions specified in § 406.13(c), and files an application, entitlement would begin with the month in which dialysis treatments are initiated or resumed, without a waiting period, subject to the basic limitations of entitlement in § 406.13(e)(1).

II. Analysis of and Responses to Public Comments

Comment: Several commenters were concerned that the proposed revision to the definition of ESRD would not achieve HCFA's stated goals of clarifying the entitlement to Medicare's ESRD benefit or eliminating the one percent alleged error rate. In fact, the change in the definition of ESRD to refer to "generally accepted diagnostic criteria and laboratory findings" could be inappropriate if HCFA attempts to establish one easily defined set of laboratory values or other criteria which represent a clear boundary between cases of ESRD and non-ESRD. One commenter remarked that patients with many comorbidities, especially cardiovascular complications, could die of heart attacks or other events while their physicians wait to put them on dialysis until their laboratory values reach an arbitrary and too strict standard. The commenters asked that any system that relies on sets of laboratory values or other criteria should provide for medical review of questionable cases by a group of knowledgeable physicians, with an opportunity for input by the physician of the patient in question.

Response: In creating the Medicare ESRD program, the Congress clearly intended that Medicare should be available only to patients who have ESRD and require regular dialysis

treatments or a kidney transplant to survive. It was certainly not our intent in proposing a change in the definition of ESRD to cause physicians to delay prescribing dialysis for patients who do not yet meet a prescribed set of laboratory values but have other comorbid conditions that the physicians believe would benefit from dialysis treatment. In fact, we have always been confident that physicians who believe that dialysis is a necessary component in treating a patient's medical condition prescribe such treatment without regard to the expectation of Medicare coverage.

After considering the comments, we now believe that changes being made in the way we review medical evidence of ESRD will accomplish more to ensure that patients meet the definition of ESRD than would a change to the definition of ESRD in the regulations. Under the screening process that is expected to be used by the ESRD networks in reviewing ESRD medical evidence report forms, patients who meet certain prescribed laboratory test values will automatically be considered to have ESRD. Cases that fail to meet the laboratory test values will then be sent to the network's medical review board for further review. At this stage, the treating physician will have the opportunity to furnish additional information on the patient's condition. Only after the medical review board has completed its review of the case and concluded that the patient's condition is not ESRD will the patient's Medicare claim be denied. Therefore, we have decided not to revise the definition of ESRD, as proposed, and are retaining the existing definition of ESRD in § 406.13(b).

Comment: The proposed rule does not address the issues of notification to HCFA to ensure continuity of benefits when a patient returns to dialysis within 12 months after regaining kidney function or during the 36 months following transplantation.

Response: The actual process used to prevent terminations from occurring when an individual resumes dialysis or receives another transplant is not appropriate for inclusion in regulations. However, in cases in which an individual ceases dialysis or receives a transplant, the individual is notified immediately that Medicare will terminate in the future (12 months after dialysis ends or 36 months after transplant) unless by that time dialysis is resumed or another transplant is received. Three months before the termination is effective, we send the individual another notice and an ESRD medical evidence form (HCFA-2728) and advise the individual to have the

form completed by the treating source without delay if dialysis has been resumed or another transplant received. We believe this process provides ample time for an individual to notify us about resumption of dialysis or receipt of a new transplant in order to prevent an incorrect termination of Medicare entitlement.

III. Provisions of the Final Regulations

Definition of ESRD—This final rule does not incorporate the proposed definition of ESRD. We are retaining the existing definition of ESRD in § 406.13(b).

Resumption of Entitlement to ESRD Benefits—We are incorporating the provisions of the proposed rule. In addition, we are making a technical revision by expanding § 406.13(g)(1) to indicate that a new period of Medicare entitlement begins if an individual receives a kidney transplant during the 12-month period after a course of dialysis ends; he or she is entitled to resume Part A benefits and eligible to enroll in Part B benefits effective with the month the transplant occurs. This was inadvertently omitted from the proposed rule and assures that both individuals who resume dialysis and those who receive a transplant during the 12-month period after a course of dialysis ends will be treated the same with respect to the right to immediately enroll in Part B benefits without having to wait for the annual general enrollment period.

IV. Collection of Information Requirements

This rule contains no information collection requirements. Consequently, this rule need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.).

V. Regulatory Impact Statement

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a final rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we consider all physicians and dialysis facilities to be small entities. Individuals are not included in the definition of a small entity.

Also, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a final 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 50 beds.

This final rule incorporates the technical provisions of the proposed rule regarding resumption of entitlement. This rule has no budget impact because it merely conforms the regulations more closely to the intent of the Social Security Act in order to avoid any ambiguity concerning the conditions for resumption of Medicare entitlement. Therefore, we are not preparing analyses for either the RFA or section 1102(b) of the Act since we have determined, and the Secretary certifies, that this final rule will not result in a significant economic impact on a substantial number of small entities and will not have a significant impact on the operations of a substantial number of small rural hospitals. In accordance with the provisions of Executive Order 12866, this regulation was not reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 406

Health facilities, Kidney diseases, Medicare.

42 CFR chapter IV, part 406 is amended as follows:

PART 406—HOSPITAL INSURANCE ELIGIBILITY AND ENTITLEMENT

1. The authority citation for part 406 continues to read as follows:

Authority: Secs. 202(t), 202(u), 226, 226A, 1102, 1818, and 1871 of the Social Security Act (42 U.S.C. 402(t), 402(u), 426, 426-1, 1302, 1395i-2, and 1395hh) and 103 of Pub. L. 89-97 (42 U.S.C. 426a) unless otherwise noted.

2. In § 406.13, paragraphs (f) and (g) are revised to read as follows:

§ 406.13 Individual who has end-stage renal disease.

* * * * *

(f) *End of entitlement.* Entitlement ends with—

(1) The end of the 12th month after the month in which a regular course of dialysis ends; or

(2) The end of the 36th month after the month in which the individual has received a kidney transplant.

(g) *Resumption of entitlement.* Entitlement is resumed under the following conditions:

(1) An individual who initiates a regular course of renal dialysis or has a kidney transplant during the 12-month period after the previous course of

dialysis ended is entitled to Part A benefits and eligible to enroll in Part B with the month the regular course of dialysis is resumed or the month the kidney is transplanted.

(2) An individual who initiates a regular course of renal dialysis or has a kidney transplant during the 36-month period after an earlier kidney transplant is entitled to Part A benefits and eligible to enroll in Part B with the month the regular course of dialysis begins or with the month the subsequent kidney transplant occurs.

(3) An individual who initiates a regular course of renal dialysis more than 12 months after the previous course of regular dialysis ended or more than 36 months after the month of a kidney transplant is eligible to enroll in Part A and Part B with the month in which the regular course of dialysis is resumed. If he or she is otherwise entitled under the conditions specified in paragraph (c) of this section, including the filing of an application, entitlement begins with the month in which dialysis is initiated or resumed, without a waiting period, subject to the limitations of paragraph (e)(1) 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: November 29, 1994.

Bruce C. Vladek,

Administrator, Health Care Financing Administration.

Dated: January 5, 1995.

Donna E. Shalala,

Secretary.

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BILLING CODE 4120-01-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Public Land Order 7139

[AZ-930-1430-01; AZA 26964]

Withdrawal of National Forest System Land for Houston Mesa Campground; Arizona

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order withdraws 320 acres of National Forest System land from mining for 20 years to protect the Houston Mesa Campground site. The land has been and will remain open to mineral leasing and other uses authorized by the Forest Service.

EFFECTIVE DATE: May 8, 1995.

FOR FURTHER INFORMATION CONTACT: John Mezes, BLM Arizona State Office, P.O. Box 16563, Phoenix, Arizona 85011, 602-650-0509.

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (1988), it is ordered as follows:

1. Subject to valid existing rights, the following described National Forest System land is hereby withdrawn from location and entry under the United States mining laws (30 U.S.C. Ch. 2 (1988)), but not from leasing under the mineral leasing laws, to protect the Houston Mesa Campground site.

Gila and Salt River Meridian

T. 11 N., R. 10 E.,

Sec. 27, N¹/₂.

The area described contains 320 acres in Gila County.

2. The withdrawal made by this order does not alter the applicability of those land laws governing the use of the National Forest System lands under lease, license or permit, or governing the disposal of their mineral or vegetative resources other than under the mining laws.

3. This withdrawal will expire 20 years from the effective date of this order unless, as a result of a review conducted before the expiration date pursuant to section 204(f) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714(f) (1988), the Secretary determines that the withdrawal be extended.

Dated: April 21, 1995.

Bob Armstrong,

Assistant Secretary of the Interior.

[FR Doc. 95-11191 Filed 5-5-95; 8:45 am]

BILLING CODE 4310-32-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 90-90; RM-7128, RM-7332, RM-7410, RM-7411, RM-7412]

FM Radio Broadcasting Services; Sulphur and South Fort Polk, LA; Bay City, Edna, Galveston, Jasper, LaGrange, New Ulm, Palacios, Redland, Rosenberg, and Winnie, TX

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document grants the rule making petition filed by KSIG Broadcasting Company, Inc.,