

1996, 1997, and 1998. We estimate that the annual drug cost following transplantation for a full time user of immunosuppressive drugs will be as follows:

ESTIMATED ANNUAL COST OF IMMUNOSUPPRESSIVE DRUGS FOR EACH TRANSPLANT PATIENT

CY 1995	CY 1996	CY 1997
\$5580	\$5910	\$6275

This final rule also differs from the proposed rule in that the term "immunosuppressive drugs" has been changed to "prescription drugs used in immunosuppressive therapy" to conform with section 4075 of OBRA '87. This expanded coverage will allow payment for other necessary drugs used in conjunction with immunosuppressive drugs.

B. Regulatory Flexibility Act

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless the Secretary certifies that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, pharmacists, physicians who perform transplantation services, and manufacturers of covered pharmaceuticals are considered to be small entities. Although pharmaceutical manufacturers are frequently not considered to be small entities, the possibility exists that certain manufacturers affected by this final rule may meet the definition of a small entity.

In addition, section 1102(b) of the Act requires the Secretary 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 50 beds.

Because of the high cost of a majority of the drugs used for immunosuppressive therapy and the extended time that beneficiaries are required to take the drugs to ensure that the transplanted organ is not rejected, all Medicare transplant patients and many small entities will benefit by this regulation. In many cases, 1 year of immunosuppressive therapy is not sufficient. Also, it is possible that we may avoid the additional cost of a

second transplant if a patient is kept on immunosuppressive drug therapy beyond the original 12 month coverage period.

We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and the Secretary certifies, that this 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.

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 410

Medical and other health services, Medicare.

For the reasons set forth in the preamble, 42 CFR chapter IV, part 410 is amended as set forth below:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

1. The authority citation continues to read as follows:

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

2. In § 410.10, the introductory text is republished and a new paragraph (u) is added to read as follows:

§ 410.10 Medical and other health services: Included services.

Subject to the conditions and limitations specified in this subpart, "medical and other health services" includes the following services:

* * * * *

(u) Prescription drugs used in immunosuppressive therapy.

3. A new § 410.31 is added to read as follows:

§ 410.31 Prescription drugs used in immunosuppressive therapy.

(a) *Scope.* Payment may be made for prescription drugs used in immunosuppressive therapy that have been approved for marketing by the FDA and that meet one of the following conditions:

(1) The approved labeling includes the indication for preventing or treating the rejection of a transplanted organ or tissue.

(2) The approved labeling includes the indication for use in conjunction with immunosuppressive drugs to prevent or treat rejection of a transplanted organ or tissue.

(3) Have been determined by a carrier (in accordance with part 421, subpart C

of this chapter), in processing a Medicare claim, to be reasonable and necessary for the specific purpose of preventing or treating the rejection of a patient's transplanted organ or tissue, or for use in conjunction with immunosuppressive drugs for the purpose of preventing or treating the rejection of a patient's transplanted organ or tissue. (In making these determinations, the carriers may consider factors such as authoritative drug compendia, current medical literature, recognized standards of medical practice, and professional medical publications.)

(b) *Period of eligibility.* Coverage is available only for prescription drugs used in immunosuppressive therapy, furnished to an individual who receives an organ or tissue transplant for which Medicare payment is made, for the following periods:

(1) For drugs furnished before 1995, for a period of up to 1 year beginning with the date of discharge from the hospital during which the covered transplant was performed.

(2) For drugs furnished during 1995, within 18 months after the date of discharge from the hospital during which the covered transplant was performed.

(3) For drugs furnished during 1996, within 24 months after the date of discharge from the hospital during which the covered transplant was performed.

(4) For drugs furnished during 1997, within 30 months after the date of discharge from the hospital during which the covered transplant was performed.

(5) For drugs furnished after 1997, within 36 months after the date of discharge from the hospital during which the covered transplant was performed.

(c) *Coverage.* Drugs are covered under this provision irrespective of whether they can be self-administered.

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

Dated: January 9, 1995.

Bruce C. Vladeck,
Administrator, Health Care Financing Administration.

Approved: February 9, 1995.

Donna E. Shalala,
Secretary.

[FR Doc. 95-3835 Filed 2-15-95; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF THE INTERIOR**Bureau of Land Management****43 CFR Public Land Order 7115**

[UT-942-1430-01; UTU-52338]

Partial Revocation of Executive Order of April 17, 1926, Public Water Reserve 107 Withdrawal; Utah

AGENCY: Bureau of Land Management.
ACTION: Public land order.

SUMMARY: This order revokes Executive Order of April 17, 1926, insofar as it affects 40.84 acres of public land withdrawn as a public water reserve. The land is no longer needed for the purpose of the withdrawal, and the revocation is needed to permit disposal of the land through a land exchange under the authority of the Federal Land Policy and Management Act of 1976. This action will open the land to surface entry, and to mining for nonmetalliferous minerals. The land has been and will remain open to mineral leasing and mining for metalliferous minerals.

EFFECTIVE DATE: March 20, 1995.

FURTHER FOR FURTHER INFORMATION

CONTACT: Randy Massey, BLM Utah State Office, P.O. Box 45155, Salt Lake City, Utah 84145-0155.

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. Executive Order of April 17, 1926, which withdrew public land containing springs and water holes as public water reserves, is hereby revoked insofar as it affects the following described land:

Salt Lake Meridian

T. 11 N., R. 19 W.,
 Sec. 4, lot 1;

The area described contains 40.84 acres in Box Elder County.

The land described above is no longer needed for the purpose for which withdrawn. There is no water on the parcel, nor evidence of any in the past.

2. At 9 a.m. on March 20, 1995, the land will be opened to the operation of the public land laws generally, subject to valid existing rights, the provision of existing withdrawals, other segregations of record, and the requirements of applicable law. All valid applications received at or prior to 9 a.m. on March 20, 1995 shall be considered as simultaneously filed at that time. Those received thereafter shall be considered in the order of filing.

3. At 9 a.m. on March 20, 1995 the land will be opened to location and

entry for nonmetalliferous minerals under the United States mining law, subject to valid existing rights, the provision of existing withdrawals, other segregations of record, and the requirements of applicable law. Appropriation of any of the land described in this order under the general mining laws prior to the date and time of restoration is unauthorized. Any such attempted appropriation, including attempted adverse possession under 30 U.S.C. 38 (1988), shall vest no rights against the United States. Acts required to establish a location and to initiate a right of possession are governed by State law where not in conflict with Federal law. The Bureau of Land Management will not intervene in disputes between rival locators over possessory rights since Congress has provided for such determinations in local courts.

Dated: February 6, 1995.

Bob Armstrong,

Assistant Secretary of the Interior.

[FR Doc. 95-3893 Filed 2-15-95; 8:45 am]

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DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 227**

[Docket No. 950201033-5033-01; I.D. 041294E]

RIN 0648-AG37

Sea Turtle Conservation; Shrimp Trawling Requirements

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: This final rule allows non-Federal entities to apply for, and NMFS to issue, permits for the incidental take of threatened species of sea turtles consistent with section 10(a) of the Endangered Species Act (ESA). Under existing regulations, the prohibitions of section 9 of the ESA apply to both endangered and threatened species, but section 10 incidental take permits may be authorized for endangered, but not threatened, species of sea turtles. This regulation corrects this discrepancy in the application of sections 9 and 10 to threatened species of sea turtles.

EFFECTIVE DATE: March 20, 1995.

ADDRESSES: Requests for copies of the Environmental Assessment (EA) for the

proposed rule, should be addressed to Endangered Species Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT:

Heather Weiner, Endangered Species Division, 301-713-1401; Doug Beach, Protected Species Program Coordinator, NMFS Northeast Regional Office, 508-281-9254; or Charles A. Oravetz, Chief, Protected Species Program, NMFS Southeast Regional Office, 813-570-5312.

SUPPLEMENTARY INFORMATION:**Background**

All sea turtles that occur in U.S. waters are listed as either endangered or threatened under the ESA. Kemp's ridley (*Lepidochelys kempii*), leatherback (*Dermodochelys coriacea*) and hawksbill (*Eretmodochelys imbricata*) turtles are listed as endangered. Loggerhead (*Caretta caretta*), green (*Chelonia mydas*) and olive ridley (*Lepidochelys olivacea*) turtles are listed as threatened, except for breeding populations of green turtles in Florida and on the Pacific Coast of Mexico, and the breeding population of olive ridley turtles on the Pacific Coast of Mexico, which are listed as endangered.

In a proposed rule published on July 21, 1994 (59 FR 37213), NMFS proposed to extend existing incidental-take permit regulations to all threatened species of sea turtles as authorized under section 10(a)(1)(B) of the ESA. Section 10 authorizes the Secretary of Commerce to permit under such terms and conditions as he or she may prescribe, any taking otherwise prohibited by section 9(a)(1)(B) of the ESA, if the taking is incidental to, and not the purpose of, carrying out an otherwise lawful activity. NMFS implemented regulations for the application and issuance of incidental-take permits, under section 10(a) of the ESA, which appear at 50 CFR parts 220 and 222, and allow the Assistant Administrator for Fisheries, NOAA, (AA) to issue permits to incidentally take endangered marine species during otherwise lawful activities.

Comments and Responses on the Proposed Rule

NMFS received responses from four commenters, including the U.S. Department of the Interior, regarding the proposed rule. Commenters were generally supportive of the proposed rule, but expressed some concerns about permit issuance and review. NMFS reviewed all comments in detail and combined their common concerns for response.