DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 409, 410, 489, and 498

[HCFA–3045–F]

Medicare Program; Removal of the Requirements for the Cardiac Pacemaker Registry

AGENCY: Health Care Financing Administration, HHS.

ACTION: Final rule.

SUMMARY: This final rule eliminates all requirements and references regarding the Cardiac Pacemaker Registry (the Registry) in our regulations. It conforms to the Food and Drug Administration's (FDA) recent final rule that required any physician and any provider of services who requests or receives Medicare payment for the implantation, removal, or replacement of permanent cardiac pacemaker devices and pacemaker leads to submit certain information to the Registry. We used the information to administer Medicare payment for these devices. This rule implements an Act to Repeal An Unnecessary Medical Device Reporting Requirement passed by Congress to eliminate duplicative and unnecessary reporting.

EFFECTIVE DATE: This regulation is effective October 19, 2000.

FOR FURTHER INFORMATION CONTACT: Shana Olshan, (410) 786–3122.

SUPPLEMENTARY INFORMATION:

I. Background

On July 23, 1987, we and the FDA jointly issued a final rule establishing the national cardiac pacemaker registry (52 FR 27756), as mandated by the Deficit Reduction Act of 1984 (Public Law 98–369). The final rule for the Registry was codified in 21 CFR part 805. The scope of the regulation provided that the FDA establish a nationwide registry for cardiac pacemakers and pacemaker leads. The FDA used the information submitted to the Registry to track the performance of permanent pacemakers and pacemaker leads and to perform studies and analysis regarding the use of the devices. They transmitted data to us to administer the Medicare program, and to other Federal components to carry out statutory responsibilities.

On October 2, 1996, An act to Repeal An Unnecessary Medical Device Reporting Requirement (Public Law 104–224), which amended title XVIII of the Social Security Act (the Act) (42 U.S.C. 1395), became law. The purpose of the new law was to remove section 1862(h) (42 U.S.C. 1395y(h)) of the Act to eliminate duplicative and unnecessary reporting. The registry was considered duplicative with the requirements of section 519(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(e)), which requires that manufacturers track and collect data for certain devices, including permanently implanted pacemakers and pacemaker leads, from the manufacturer, through the distribution chain, to the patient using the device. In accordance with this act, the FDA published a final rule in the **Federal Register** revoking the Registry on November 24, 1999 (64 FR 66105).

II. Provisions of the Regulation

In response to the FDA revocation of the Registry, we are removing all requirements and references regarding the Registry that appear in our regulations. These appear in 42 CFR Parts 409, 410, 489, and 498. We are revising § 409.1(e) to remove the phrase ''* * * and section 1862(h) requires a registry of pacemakers.'' We are also removing §§ 409.19 and 410.64, which deal exclusively with requirements for providers and physicians related to the Registry. And we are removing and reserving §§ 489.21(g) and 498.3(b)(10), which contain cross references to §§ 409.19 and 410.64.

III. Waiver of Proposed Rulemaking and Delayed Effective Date

Under section 553(b)(B) of the Administrative Procedure Act (APA), we, for good cause, find that notice and comment procedures are unnecessary because we are not exercising discretion in removing the references to the Registry. And, under section 553(d)(3) of the APA, we, for good cause, waive the 30-day delay in the effective date because Public Law 104–224 was self-implementing.

IV. Regulatory Impact Analysis

We have reviewed this notice under the threshold criteria of Executive Order 13132. We have determined that this final rule will not have substantial direct effects on the states, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million in any one year. This final rule will not have an effect on the governments mentioned, and the private sector costs will not be greater than the $100 million threshold.

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 1980 Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). This rule is not a major rule because costs will not meet this $100 million threshold. The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $5 million or less annually. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

In accordance with the provisions of Executive Order 12866, this final rule was not reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Rural areas, X-rays.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 42 CFR Chapter IV is amended as follows:

PART 409—HOSPITAL INSURANCE BENEFITS

A. Part 409 is amended as set forth below.

1. The authority citation for part 409 is revised to read as follows:

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

2. In § 409.1, paragraph (e) is revised to read as follows:

§ 409.1 Statutory basis.

* * * * *

(e) Section 1862(a) specifies exclusions from coverage.

* * * * *

3. Section 409.19 is removed.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

B. Part 410 is amended as set forth below.

1. The authority citation for part 410 continues to read as follows:

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

§ 410.64 [Removed]

2. Section 410.64 is removed.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

C. Part 489 is amended as set forth below.

1. The authority citation for part 489 continues to read as follows:

Authority: Secs. 1102, 1819, 1861, 1864(m), 1866, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, and 1395hh).

§ 489.21 [Amended]

2. In § 489.21, paragraph (g) is removed and reserved.

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFS/MR AND CERTAIN NFS IN THE MEDICAID PROGRAM

D. Part 498 is amended as set forth below.

1. The authority citation for part 498 continues to read as follows:

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

§ 498.3 [Amended]

2. In § 498.3, paragraph (b)(11) is removed and reserved.

Authority: Secs. 1102, 1819, 1861, 1864(m), 1866, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, 1395hh, and 1895hh).

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

Dated: April 18, 2000.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Dated: May 31, 2000.

Donna E. Shalala,

Secretary.

[FR Doc. 00–26282 Filed 10–18–00; 8:45 am]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 20

[CC Docket No. 94–54; FCC 00–251]

Interconnection and Resale Obligations Pertaining to Commercial Mobile Radio Services; Correction

AGENCY: Federal Communications Commission.

ACTION: Final rule; correction.

SUMMARY: On September 29, 2000, the Commission published a document in the **Federal Register** which established service rules governing the manual roaming responsibilities of Commercial Mobile Radio Services (CMRS) providers. This document makes corrections to that document.

DATES: Effective November 28, 2000.

FOR FURTHER INFORMATION CONTACT: Paul Murray at (202) 418–7240.

SUPPLEMENTARY INFORMATION: The Commission, in its summary of the Memorandum Opinion and Order (MO&O), FR Doc. 00–24964, published in the **Federal Register** of September 29, 2000 (65 FR 58477) released information that requires correction. First, it misstated the correct agency docket number for the item (CC Docket No. 94–54) in the headings section. Then, in the **SUPPLEMENTARY INFORMATION** section of the preamble, the Commission erroneously incorporated a docket number and the associated adoption and release dates from another proceeding into this item thereby omitting the correct docket number for this proceeding (CC Docket No. 94–54), the correct adoption date of the MO&O (July 13, 2000), and the correct release date of the MO&O (August 28, 2000). Further, this item corrects the phone listing for Paul Murray to 418–7240.

In FR Doc. 00–24964, published in the **Federal Register** of September 29, 2000 (65 FR 58477), make the following corrections:

(1) On page 58477, in the second column, in the Agency Docket number, correct ''PR Docket No. 94–54'' to read ''CC Docket No. 94–54.''

(2) On the same page, in the third column, line four, correct ''(202) 418–0688'' to read ''(202) 418–7240.''

(3) On the same page, in the same column, line 11, correct ''PR Docket No. 93–144'' to read ''CC Docket No. 94–54.''

(4) On the same page, in the same column, line 12, correct ''August 2, 2000'' to read ''July 13, 2000.''

(5) On the same page, in the same column, lines 12 and 13, correct ''August 4, 2000'' to read ''August 28, 2000.''

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 00–26893 Filed 10–18–00; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 000211040–0040–01; I.D. 101200A]

Fisheries of the Exclusive Economic Zone Off Alaska; Reallocation of Pollock

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

ACTION: Reallocation.

SUMMARY: NMFS is reallocating projected unused amounts of Bering Sea