DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 486

[CMS–3064–IFC]

RIN 0938–AK81

Medicare and Medicaid Programs; Emergency Recertification for Coverage for Organ Procurement Organizations (OPOs)

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

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period recertifies the existing designated organ procurement organizations (OPOs) that meet, or have met, the standards for a qualified OPO within a 4 year period ending December 31, 2001 and have current agreements with the Secretary that are scheduled to terminate on July 31, 2002. Those agreements will be extended to July 31, 2006. The Organ Procurement Organization Certification Act of 2000 amended the Public Health Service Act to require CMS to increase the certification cycle for OPOs from 2 years to at least 4 years. We are issuing this interim final rule to establish a 4 year recertification cycle and to permit payments to continue to be made to all 59 OPOs after January 1, 2002.

DATES: Effective date: These regulations are effective on December 28, 2001.

Comment date: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on February 26, 2002.

ADDRESSES: In commenting, please refer to file code CMS–3064–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Mail written comments (one original and three copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3064–IFC, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and three copies) to one of the following addresses:

Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–16–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Jacqueline Morgan, (410) 786–4282.

Marcia Newton (410) 786–5265.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, call telephone number (410) 786–9994.

I. Background

Organ procurement organizations (OPOs) play a crucial role in ensuring that an immensely valuable but scarce resource-transplantable human organs-become available to seriously ill patients who are on waiting lists for organ transplant. OPOs are government contractors for the length of their contract cycle. They are responsible for identifying potential organ donors and for obtaining as many organs as possible from those donors. They are also responsible for ensuring that the organs they obtain are properly preserved and quickly delivered to a suitable recipient awaiting transplantation. OPO performance is therefore a critical element of the organ transplant program. An OPO that is efficient in procuring organs and delivering them to recipients will, quite literally, save more lives than an ineffective OPO. Among other things, Congress has directed the Secretary to establish performance standards for OPOs, to ensure that federal funds go primarily to the most efficient OPOs and to ensure that OPOs have an incentive to achieve higher performance.

In order to be an OPO, an entity must be certified or recertified by CMS as meeting the Public Health Service Act requirements to be a qualified OPO and must meet performance standards specified by the Secretary. In addition, in order to receive payment under the Medicare and Medicaid programs for organ procurement costs, the entity must be designated or redesignated by CMS as the OPO for a defined geographic service area.

There are 59 OPOs that have been certified by CMS and designated for specific geographic service areas. At the conclusion of the most recent performance data cycle (the cycle in which we analyzed OPO performance data generated during the period of January 1, 1998 through December 31, 1999), 56 of the 59 OPOs were found by CMS to have met the performance standards and agreements were made through July 31, 2002. After additional legislation was enacted in November 2000, those three OPOs that did not meet the performance standards were notified by CMS on November 17, 2000 that their agreements were extended through July 31, 2002, based on section 1138(b)(1)(A) of the Social Security Act. Each of these three OPOs had been certified or recertified as meeting the performance standards for the previous 2 year performance period (January 1, 1996 through December 31, 1997.)

We are promulgating these rules to increase the OPO recertification period from 2 years to 4 years, in order to be consistent with the period described in the new statute. We are also recertifying all 59 OPOs and extending agreeements with these OPOs until July 31, 2006. We have chosen July 31, 2006 as the ending date of the agreement because our contracts with designated OPOs have historically ended on July 31.

We will publish a separate notice of proposed rulemaking that, among other things, will set forth proposed outcome and process performance standards for OPOs based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each service area.

II. Provisions of the Interim Final Rule

We are establishing a new § 486.309, Recertification for the January 1, 2002 through December 31, 2005 period. This section specifies that OPOs that were certified by CMS in the past and currently have agreements with CMS are recertified. The current agreements will be extended through July 31, 2006.

Additionally, we are amending § 486.301 by adding a new paragraph (b)(4) to reflect this change in the scope of the subpart.

III. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all

comments we receive by the date and time specified in the ''**DATES**'' section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IV. Waiver of Proposed Rulemaking and Delayed Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued (5 U.S.C. 553(b)(3)(B)).

Further, we generally provide for final rules to be effective no sooner than 30 days after the date of publication unless we find good cause under 5 U.S.C. 553(d)(3) to waive the delay. The purpose of the 30-day waiting period between publication of an administrative agency final rule and its effective date is to give affected parties reasonable time to adjust their behavior before the final rule takes place. This 30-day delay can be waived for good cause.

Section 701 of Pub. L. 106–505 was enacted on November 13, 2000. Section 701(b) included Congressional findings and section 701(c) amended 42 U.S.C. 273(b)(1) to state that a qualified organ procurement organization for which grants are made under 42 U.S.C 273(a) must meet the other requirements of 42 U.S.C. 273 and has been certified or recertified by the Secretary within the previous 4-year period as meeting the performance standards to be a qualified OPO, through a process that either granted certification or recertification within such 4-year period with such certification or recertification in effect as of January 1, 2001 and remaining in effect through the earlier of January 1, 2002 or the completion of recertification through regulations meeting the requirements of 42 U.S.C. 273(b)(1)(D)(ii) that are promulgated by the Secretary by not later than January 1, 2002. Congress then enacted section 219 of Pub. L. 106–554 on December 21, 2000. Section 219(a)–(b) is identical to the language of section 701(b)–(c) in Pub. L. 106–505.

The statute requires CMS to recertify OPOs and to establish at least a 4-year recertification period by January 1, 2002. Otherwise, OPOs would not be certified and we would be unable to make payments to OPOs (or to hospitals on behalf of OPOs) after that date. As discussed later in this preamble, this would put the nation's organ procurement system in jeopardy.

When the legislation was enacted, CMS had just been briefed (November 15, 2000) on results from the Association of Organ Procurement Organization's (AOPO's) model for estimating organ donation potential in hospitals. CMS was in the process of analyzing a similar model developed by the Partnership for Organ Donation and the Harvard School of Public Health, following the completion of a 1-year contract with Harvard to apply their model nationwide. CMS met with AOPO representatives and researchers from the AOPO Death Record Review (DRR) study twice in late January 2001 for further analysis of the AOPO study results and to discuss possible denominators for the numeric performance standards. AOPO's written recommendations for new performance standards were received in March and April 2001, and CMS staff continued discussions with AOPO through May 2001 to gain additional industry input. Analysis of the Harvard and AOPO models continued throughout this time.

CMS concluded that the time needed to develop accurate new performance standards ''based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors'' precluded the possibility of completing all of the required rulemaking by the statutory timeframe. Therefore, the agency is publishing an interim final rule with comment that recertifies all 59 OPOs. We are also extending our agreements with all 59 of the current OPOs until July 31, 2006, on the basis of our observations and experience with those OPOs.

According to section 371(b) of the Public Health Service Act, an OPO must be a ''qualified'' OPO, as determined by the Secretary. According to section 1138 of the Social Security Act, an OPO must be certified or recertified by the Secretary as meeting the standards to be a qualified OPO, must meet performance-related standards prescribed by the Secretary, and must be designated by the Secretary as an OPO in order to receive reimbursement under title XVIII or title XIX. Because section 273(b)(1)(D)(i) would terminate certifications after January 1, 2002, we are issuing this interim final rule to permit all 59 OPOs to continue to function, procure organs and obtain appropriate reimbursement.

The nation's 59 OPOs are responsible for all cadaveric organ recovery in the United States; without OPOs, cadaveric organs will not be recovered. Without recovery of cadaveric organs, very few organ transplants will take place. That is, only organs from living donors would be recovered and transplanted.

As of October 31, 2001, there were 78,518 men, women, and children waiting for an organ transplant. Many of them will die waiting. In fact, every day, more than 15 patients die waiting for an organ. In 2000, there were 17,255 transplants of organs from cadaveric donors, or nearly 47 transplants per day from cadaveric donors. This means that even a 1-day disruption in the nation's organ procurement system could result in the deaths of 47 patients waiting for organs. A 1-week disruption to the nation's organ procurement system could result in the deaths of 329 patients waiting for organs, and a 1-month disruption could result in 1,410 deaths.

Clearly, it is critical that OPOs be recertified by January 1, 2002 in order to continue this work. It would be contrary to the public interest to delay recertifying OPOs until after new outcome and process performance standards were established through notice and comment procedures. Moreover, because OPOs that are currently experienced in providing these services will continue to do so on January 1, 2002, they will not require additional time to prepare to implement these rules. Thus, there is good cause to waive the 30-day delay in effective date established by 5 U.S.C. 553(d). Therefore, we have chosen to publish a final rule with comment recertifying all 59 existing OPOs and establishing a 4-year recertification cycle. Publication as an immediately effective final rule will avert the impending problem that would occur under section 273(b)(1)(D)(i) after January 1, 2002.

Therefore, we find good cause to waive the notice of proposed rulemaking and to issue this final rule on an interim basis. We are providing a 60-day public comment period.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

VI. Regulatory Impact Statement

A. Overall Impact

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 Pub. L. 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 interim final rule is not a major rule. It does not have any cost or savings impact as it merely recertifies the existing 59 OPOs and does not introduce any new requirements.

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 $25 million or less annually. For purposes of the RFA, all OPOs are considered to be small entities. 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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in anyone year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This rule will not have an effect on the governments mentioned, nor does it have associated private sector costs. This rule does not have any cost or savings impact as it extends the time period for payments under existing agreements and does not introduce any new requirements.

According to section 1138 of the Social Security Act, an OPO must be certified or recertified by the Secretary as meeting the standards to be a qualified OPO, must meet performance-related standards prescribed by the Secretary, and must be designated by the Secretary as an OPO in order to receive reimbursement under title XVIII or title XIX. Because section 273(b)(1)(D)(i) would terminate certifications after January 1, 2002, we are issuing this interim final rule to permit all 59 OPOs to continue to function, procure organs and obtain appropriate reimbursement.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. As stated previously, this rule does not have a substantial effect on State or local governments.

B. Conclusion

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, 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 reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 486

Health professionals, Medicare, Organ procurement, X-rays.

PART 486—CONDITIONS OF COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services is amending 42 CFR chapter IV as set forth below:

1. The authority citation for part 486 continues to read as follows:

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

Subpart G—Conditions of Coverage: Organ Procurement Organizations

2. Section 486.301 is amended by adding paragraph (b)(4) to read as follows:

§ 486.301 Basis and scope.

* * * * *

(b) * * *

(4) The requirements for an OPO to be recertified for the performance data cycle from January 1, 2002 through December 31, 2005.

3. Section 486.309 is added to read as follows:

§ 486.309 Recertification from January 1, 2002 through December 31, 2005.

An OPO will be considered to be recertified for the period of January 1, 2002 through December 31, 2005 if an entity meets, or has met, the standards to be a qualified OPO within a four year period ending December 31, 2001 and has an agreement with the Secretary that was scheduled to terminate on July 31, 2002. Agreements based on this recertification will end on July 31, 2006.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

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

Dated: December 7, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Approved: December 14, 2001.

Tommy G. Thompson,

Secretary.

[FR Doc. 01–31724 Filed 12–21–01; 11:04 am]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 43, and 63

[DA 01–2825]

Removal of References to Sections in the Commission's Rules That No Longer Exist

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document the Commission amends references to sections that have been removed from the Commission's rules and amends a section heading.

DATES: Effective December 28, 2001.

FOR FURTHER INFORMATION CONTACT: Peggy Reitzel, Telecommunications Division, International Bureau, at (202) 418–1499.

SUPPLEMENTARY INFORMATION: We have removed references to sections in the