

be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Requirements in HSQ-110, Acquisition, Protection and Disclosure of Peer Review Organization Information and Supporting Regulations in 42 CFR, Sections 480.104, 480.105, 480.116, and 480.134.; *Form No.:* CMS-R-70 (OMB# 0938-0426); *Use:* The Peer Review Improvement Act of 1982 authorizes quality improvement organizations (QIOs), formally known as PROs, to acquire information necessary to fulfill their duties and functions and places limits on disclosure of the information. These requirements are on the QIOs to provide notices to the affected parties when disclosing information about them. These requirements serve to protect the rights of the affected parties. *Frequency:* On occasion; *Affected Public:* Business or other for-profit, Individuals or Households, and Not-for-profit institutions; *Number of Respondents:* 362; *Total Annual Responses:* 3,729; *Total Annual Hours:* 60,919.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Statement of Deficiencies and Plan of Correction and Supporting Regulations in 42 CFR 488.18, 488.26, and 488.28; *Form No.:* CMS-2567 (OMB# 0938-0391); *Use:* This Paperwork package provides information regarding the form used by the Medicare, Medicaid, and the Clinical Laboratory Improvement Amendments (CLIA) programs to document a health care facility's compliance or noncompliance (deficiencies) with regard to the Medicare/Medicaid Conditions of Participation and Coverage, the requirements for participation for Skilled Nursing Facilities and Nursing Facilities, and for certification under CLIA. This form becomes the basis for both public disclosure of information and CMS certification decisions (including termination or denial of participation); *Frequency:* Biennially and Annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions, Federal Government, and State, Local or Tribal Government; *Number of Respondents:* 60,000; *Total Annual Responses:* 60,000; *Total Annual Hours:* 120,000.

3. *Type of Information Collection Request:* Reinstatement, with change, of a previously approved collection for

which approval has expired; *Title of Information Collection:* Determining Third Party Liability (TPL) State Plan Preprint and Supporting Regulations in 42 CFR 433.138; *Form No.:* CMS-R-107 (OMB# 0938-0502); *Use:* The collection of third party liability information results in significant program savings to the extent that liable third parties can be identified and payments can be made for services that would otherwise be paid for by the Medicaid program. *Frequency:* On occasion; *Affected Public:* Individuals or Households, Federal Government, and State, Local, or Tribal Government; *Number of Respondents:* 1,900,000; *Total Annual Responses:* 1,900,000; *Total Annual Hours:* 329,965.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at <http://cms.hhs.gov/regulations/pr/default.asp>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: November 14, 2002.

John P. Burke III,

Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances.

[FR Doc. 02-29711 Filed 11-21-02; 8:45 am]

BILLING CODE 4120-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1241-NC]

RIN 0938-AM37

Medicare and Medicaid Programs; Announcement of Applications From Hospitals Requesting Waivers for Organ Procurement Service Areas

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

ACTION: Notice with comment period.

SUMMARY: This notice announces three applications that we have received from

hospitals requesting waivers from entering into agreements with their designated organ procurement organizations (OPOs), in accordance with section 1138(a)(2) of the Social Security Act. This notice requests comments from OPOs and the general public for our consideration in determining whether we should grant these waivers.

COMMENT DATE: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on January 21, 2003.

ADDRESSES: In commenting, please refer to file code CMS-1241-NC. Because of staffing 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-1241-NC, PO Box 8010, Baltimore, MD 21244-8010.

To ensure that mailed comments are received in time for us to consider them, please allow for possible delays in delivering them.

If you prefer, you may deliver 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 C5-09-26, 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: Mark A. Horney, (410) 786-4554.

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 Blvd., 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, phone (410) 786-9994.

I. Background

Organ Procurement Organizations (OPOs) are not-for-profit organizations that collect human organs from

hospitals and distribute them to transplant centers around the country. Qualified OPOs are designated by the Centers for Medicare & Medicaid Services (CMS) to collect organs in CMS-defined exclusive geographic service areas, according to section 371(b)(1)(F) of the Public Health Service Act (42 U.S.C. 273(b)(1)(F)) and our regulations at 42 CFR 486.307. Once an OPO has been designated for an area, hospitals in that area that participate in Medicare and Medicaid are required to work with that OPO in providing organs for transplant, according to section 1138(a) of the Social Security Act (the Act), and our regulations at § 482.45.

Section 1138(a)(1)(A)(iii) of the Act provides that a hospital must notify the designated OPO (for the service area in which it is located) of potential organ donors. Under section 1138(a)(1)(C) of the Act, every participating hospital must have an agreement to identify potential donors only with that particular designated OPO.

However, section 1138(a)(2) of the Act provides that a hospital may obtain a waiver of these requirements from the Secretary under certain specified conditions. A waiver allows the hospital to have an agreement with an OPO, other than the one initially designated by CMS, if the hospital meets certain conditions specified in section 1138(a)(2) of the Act. In addition, the Secretary may review additional criteria described in section 1138(a)(2)(B) of the

Act to evaluate the hospital's request for a waiver.

Section 1138(a)(2)(A) of the Act states that in granting a waiver, the Secretary must determine that the waiver—(1) Is expected to increase organ donations; and (2) will ensure equitable treatment of patients referred for transplants within the service area served by the designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement under the waiver. In making a waiver determination, section 1138(a)(2)(B) of the Act provides that the Secretary may consider, among other factors: (1) Cost-effectiveness; (2) improvements in quality; (3) whether there has been any change in a hospital's designated OPO due to the changes made in definitions for metropolitan statistical areas (MSAs); and (4) the length and continuity of a hospital's relationship with an OPO other than the hospital's designated OPO. Under section 1138(a)(2)(D) of the Act, the Secretary is required to publish a notice of any waiver application within 30 days of receiving the application and offer interested parties an opportunity to comment in writing for 60 days, beginning on the publication date in the **Federal Register**.

The criteria that the Secretary uses to evaluate the waiver in these cases are the same as those described above under sections 1138(a)(2)(A) and (B) of the Act and have been incorporated into the regulations at § 486.316(e) and (f).

II. Waiver Request Procedures

In October 1995, we issued a Program Memorandum (Transmittal No. A-95-11) detailing the waiver process and discussing the information that hospitals must provide in requesting a waiver. We indicated that upon receipt of the waiver requests, we would publish a **Federal Register** notice to solicit public comments, as required by section 1138(a)(2)(D) of the Act.

According to these requirements, we will review the requests and comments received. During the review process, we may consult on an as-needed basis with the Public Health Service's Division of Transplantation, the United Network for Organ Sharing, and our regional offices. If necessary, we may request additional clarifying information from the applying hospital or others. We will then make a final determination on the waiver requests and notify the affected hospitals and OPOs.

III. Hospital Waiver Requests

As permitted by § 486.316(e), three hospitals have requested waivers in order to enter into agreements with alternative, out-of-area OPOs. The listing below indicates the name of the facility, the city and State of the facility, the requested OPO, and the currently designated area OPO. These hospitals must continue to work with their designated OPOs until the completion of our review.

Name of facility	City	State	Requested OPO	Designated OPO
Pontotoc Health Services	Pontotoc	MS	MSOP	TNMS
Clay County Medical Center	West Point	MS	MSOP	TNMS
luca Hospital	luca	MS	MSOP	TNMS

IV. Keys to the OPO Codes

The keys to the acronyms used in the listings to identify OPOs and their addresses are as follows:

- MSOP—Mississippi Organ Recovery Agency, Inc., 12 River Bend Place, Jackson, Mississippi 39208
- TNMS—Mid-South Transplant Foundation, Inc., 910 Madison Avenue, Suite 1002, Memphis, Tennessee 38103

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and

approval. In order to fairly evaluate whether an information collection requirement should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques or other forms of information technology.

Section 486.316 sets forth the requirements for a Medicare or

Medicaid participating hospital to request a waiver permitting the hospital to have an agreement with an OPO other than the OPO designated for the service area in which the hospital is located. The burden associated with these requirements is currently approved under OMB 0938-0688, HCFA-R-13, Conditions of Coverage for Organ Procurement Organizations, with an expiration date of February 28, 2003.

VI. Regulatory Impact Statement

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded

Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) 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 in any 1 year). We have determined that this is not a major rule because it does not impose an economically significant impact on covered entities or the Medicare program.

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. Individuals and States are not included in the definition of a small entity. This notice will not result in a significant impact on small businesses because the notice simply announces three applications we have received from hospitals requesting waivers from entering into agreements with their designated OPOs.

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 100 beds. This notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

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 any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This notice will not result in an impact of \$110 million or more on the governments mentioned or on the private sector.

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. We have reviewed this notice under these requirements and have determined that it will not impose substantial direct requirement costs on State or local governments.

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 notice will not have a significant economic impact on the operations of a substantial number of small rural hospitals.

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

Authority: Sec. 1138 of the Social Security Act (42 U.S.C. 1320b-8).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare-Hospital Insurance; Program No. 93.774, Medicare-Supplementary Medical Insurance, and Program No. 93.778, Medical Assistance Program)

Dated: November 18, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 02-29796 Filed 11-21-02; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-2154-FN]

Medicare and Medicaid Programs; Application by the Joint Commission on Accreditation of Healthcare Organizations for Continued Deeming Authority for Ambulatory Surgical Centers

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This notice announces our decision to re-approve the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) as a national accreditation program for Ambulatory Surgical Centers (ASCs) seeking to participate in the Medicare program. Following our evaluation of the organizational and programmatic capabilities of JCAHO, we have determined that JCAHO standards for ASCs meet or exceed the Medicare conditions for coverage. Therefore, ASCs accredited by JCAHO will receive deemed status under the Medicare program.

EFFECTIVE DATE: This final notice is effective December 20, 2002 through December 20, 2008.

FOR FURTHER INFORMATION CONTACT: Cindy Melanson, (410) 786-0310.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in an ambulatory surgical center (ASC), provided that the ASC meets certain requirements. Section 1832(a)(2)(F)(i) of the Social Security Act (the Act) authorizes the Secretary of the Department of Health and Human Services (the Secretary) to establish distinct criteria for facilities seeking designation as ASCs. Under this authority, the Secretary has set forth in regulations minimum requirements that an ASC must meet in order to participate in Medicare. The regulations concerning supplier agreements are at 42 CFR part 489 and those pertaining to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 416 specify the conditions that an ASC must meet in order to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for facility services.

Generally, in order to enter into an agreement, an ASC must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 416 of our regulations. Then, the ASC is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements. There is an alternative, however, to surveys by State agencies.

Section 1865(b)(1) of the Act provides that, if a provider entity demonstrates through accreditation that all applicable Medicare conditions are met or exceeded, the Centers for Medicare & Medicaid Services (CMS) shall "deem" those provider entities to have met the requirements. Accreditation by an accreditation organization is voluntary and is not required for Medicare participation.

If an accreditation organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national accreditation organization applying for approval of deeming authority under part 488, subpart A must provide us with reasonable assurance that the accreditation organization requires the