of accredited laboratories; and its announced or unannounced inspection process.

Our evaluation identified Joint Commission requirements pertaining to waived testing that are more stringent than the CLIA requirements. The Joint Commission waived testing requirements include the following:

- Defining the extent that waived test results are used in patient care.
- Identifying the personnel responsible for performing and supervising waived testing.
- Assuring that personnel performing waived testing have adequate, specific training and orientation to perform the testing and can demonstrate satisfactory levels of performance.
- Making certain that policies and procedures governing waived testing-related processes are current and readily available.
- Conducting defined quality control checks.
- Maintaining quality control and test records.

The CLIA requirements at § 493.15 only require that a laboratory follow manufacturer's instructions and obtain a certificate of waiver.

Subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

The Joint Commission's requirements are equal to the CLIA requirements at § 493.801 through § 493.865.

Subpart J—Facility Administration for Nonwaived Testing

The Joint Commission requirements are equal to the CLIA requirements at § 493.1100 through § 493.1105.

Subpart K—Quality System for Nonwaived Testing

The Joint Commission requirements are equal to or more stringent than the CLIA requirements at § 493.1200 through § 493.1299. We have determined that Joint Commission's requirements, when taken as a whole, are more stringent than the CLIA requirements. For instance, the Joint Commission has control procedure requirements for all waived complexity testing performed.

Subpart M—Personnel for Nonwaived Testing

We have determined that the Joint Commission requirements are equal to or more stringent than the CLIA requirements at § 493.1403 through § 493.1495 for laboratories that perform moderate and high complexity testing.

Subpart Q—Inspections

We have determined that the Joint Commission requirements are equal to or more stringent than the CLIA requirements at § 493.1771 through § 493.1780. The Joint Commission will continue to perform onsite inspections every 2 years.

Subpart R—Enforcement Procedures

The Joint Commssion meets the requirements of subpart R to the extent that it applies to accreditation organizations. The Joint Commission policy sets forth the actions the organization takes when laboratories it accredits do not comply with its requirements and standards for accreditation. When appropriate, the Joint Commission will deny, suspend, or, revoke accreditation in a laboratory accredited by the Joint Commission and report that action to us within 30 days. The Joint Commission also provides an appeal process for laboratories that have had accreditation denied, suspended, or revoked.

We have determined that the Joint Commission's laboratory enforcement and appeal policies are equal to or more stringent than the requirements of part 493 subpart R as they apply to accreditation organizations.

IV. Federal Validation Inspections and Continuing Oversight

The Federal validation inspections of Joint Commission accredited laboratories may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (that is, complaint inspections). The outcome of those validation inspections, performed by us or our agents, or the State survey agencies, will be our principal means for verifying that the laboratories accredited by the Joint Commission remain in compliance with CLIA requirements. This Federal monitoring is an ongoing process.

V. Removal of Approval as an Accrediting Organization

Our regulations provide that we may rescind the approval of an accreditation organization, such as that of the Joint Commission, for cause, before the end of the effective date of approval. If we determine that the Joint Commission failed to adopt requirements that are equal to, or more stringent than, the CLIA requirements, or that systemic problems exist in its inspection process, we may give it a probationary period, not to exceed 1 year to allow the Joint Commission to adopt comparable requirements.

Should circumstances result in our withdrawal of the Joint Commission's approval, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

VI. Collection of Information Requirements

This notice does not impose any information collection and record keeping requirements subject to the Paperwork Reduction Act (PRA). Consequently, it does not need to be reviewed by the Office of Management and Budget (OMB) under the authority of the PRA. The requirements associated with the accreditation process for clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program, codified in 42 CFR part 493 subpart E, are currently approved by OMB under OMB approval number 0938–0686.

VII. Executive Order 12866 Statement

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

Authority: Section 353 of the Public Health Service Act (42 U.S.C. 263a).

Dated: December 7, 2006.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E7–3030 Filed 2–22–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1391–NC]

Medicare and Medicaid Programs; Announcement of an Application From a Hospital Requesting Waiver for Organ Procurement Service Area

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

ACTION: Notice with comment period.

SUMMARY: This notice announces a hospital's request for a waiver from entering into an agreement with its designated organ procurement organization (OPO), in accordance with section 1138(a)(2) of the Social Security Act (the Act). This notice requests comments from OPOs and the general public for our consideration in determining whether we should grant the requested waiver.

DATES: *Comment Date:* To be assured consideration, comments must be

received at one of the addresses provided below, no later than 5 p.m. on April 24, 2007.

ADDRESSES: In commenting, please refer to file code CMS–1391–NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/eRulemaking.* Click on the link ''Submit electronic comments on CMS regulations with an open comment period.'' (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–1391–NC, P.O. Box 8017, Baltimore, MD 21244–8017.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–1391–NC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT: Mark A. Horney, (410) 786–4554.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this proposed notice to assist us in fully considering the issues. You can assist us by referencing the file code CMS–1391–NC and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all electronic comments received before the close of the comment period on its public Web site as soon as possible after they have been received: *http://www.cms.hhs.gov/eRulemaking.* Click on the link ''Electronic Comments on CMS Regulations'' on that Web site to view public comments.

Comments received timely will also 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, phone 1–800–743–3951.

I. Background

[If you choose to comment on issues in this section, please include the caption ''BACKGROUND'' at the beginning of your comments.]

Organ Procurement Organizations (OPOs) are not-for-profit organizations that are responsible for the procurement, preservation, and transport of transplantable organs to transplant centers throughout the country. Qualified OPOs are designated by the Centers for Medicare & Medicaid Services (CMS) to recover or procur 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 486.306. 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)(1)(C) of the Social Security Act (the Act), and our regulations at 42 CFR 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 its designated OPO.

However, section 1138(a)(2)(A) of the Act provides that a hospital may obtain from the Secretary, a waiver of the above requirements 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)(A) 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; 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 received from a hospital within 30 days of receiving the application, and to offer interested parties an opportunity to comment in writing during the 60-day period 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 42 CFR 486.308(e) and (f).

II. Waiver Request Procedures

[If you choose to comment on issues in this section, please include the caption ''Waiver Request Procedures'' at the beginning of your comments.]

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 a waiver request, 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 request 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 request and notify the hospital and the designated and requested OPOs.

III. Hospital Waiver Request

[If you choose to comment on issues in this section, please include the caption ''Hospital Waiver Request'' at the beginning of your comments.]

As permitted by 42 CFR 486.308(e), Methodist Hospital, of Henderson, Kentucky has requested a waiver in order to enter into an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located.

Methodist Hospital is requesting a waiver to work with: Kentucky Organ Donor Affiliates, 106 East Broadway, Louisville, Kentucky 40202.

Methodist Hospital's Designated OPO is: Indiana Organ Procurement Organization, 429 N. Pennsylvania, Suite 201, Indianapolis, Indiana 46204.

Authority: Section 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: February 15, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E7–3044 Filed 2–22–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1553–N]

Medicare Program; Notice of Supplemental Election Period for Provider Participation in the Calendar Year (CY) 2007 Competitive Acquisition Plan for Part B Drugs

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

ACTION: Notice.

SUMMARY: This notice announces an additional physician election period for physicians who are not currently participating in the competitive acquisition program (CAP) for Medicare Part B drugs for calendar year (CY) 2007. The additional physician election period begins on May 1, 2007 and ends on June 15, 2007. Physicians who elect to join the CAP during this additional election period will enter into a physician election agreement effective August 1, 2007 through December 31, 2007.

DATES: The additional CAP physician election period will begin on May 1, 2007 and end on June 15, 2007. Physicians electing to join the CAP during this period will participate in the CAP effective August 1, 2007.

FOR FURTHER INFORMATION CONTACT: Edmund Kasaitis (410) 786–4545.

SUPPLEMENTARY INFORMATION:

I. Background

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) (MMA) requires the implementation of a competitive acquisition program (CAP) for certain Medicare Part B drugs not paid on a cost or prospective payment system basis. Physicians who elect to participate in the CAP obtain Medicare covered drugs from vendors selected through a competitive bidding process. Physicians who do not elect to participate in the CAP purchase these drugs and are paid under the average sales price (ASP) system. (For more information on the CAP, see the March 4, 2005 proposed rule (70 FR 10746), July 6, 2005 interim final rule with comment period (70 FR 39022), and November 21, 2005 final rule (70 FR 70116).) In accordance with the CAP statute and regulations, the regular, annual CAP physician election period for CY 2008 will occur in the fall of 2007.

II. Provisions of the Notice

Under the authority described in section 1847B(a)(5)(A)(i) of Social Security Act (the Act) and § 414.908(a)(2) of our regulations, which allows for physician election at times other than the regular, annual election period in such exigent circumstances as defined by CMS, we are designating an additional election period for physicians who wish to join the CAP. We are providing for this additional election period in recognition of the statutory change to the CAP under division B, title I, section 108 of the Tax Relief and Health Care Act of 2006 (Pub. L. 109–432) (TRHCA), effective for drugs supplied under the CAP as of April 1, 2007. We expect to provide program instructions or other guidance in the near future to implement changes to the CAP resulting from the new statutory provisions. Although the statutory change does not directly affect participating CAP physicians, it will require additional implementation efforts by CMS and was enacted after the close of the CAP physician election period for CY 2007. Thus, we believe this is an ''exigent circumstance'' for which we should allow physicians an additional opportunity to join the CAP.

The additional election period—

- Begins May 1, 2007 and end June 15, 2007; and
- Is only for physicians as defined in section 1861(r) of the Act who are not currently participating in the CY 2007 CAP.

The procedures and forms used for the regular, annual election period for CY 2007 also will be used for this additional CY 2007 election period. The aforementioned forms include the Competitive Acquisition Program (CAP) for Medicare Part B Drugs CAP Physician Election Agreement, which is currently approved under the Office of Management and Budget control number 0938–0987, with an expiration date of April 30, 2009. Physicians who wish to join the CAP during this election period may obtain a Physician Election Agreement form from the download section of the CAP Information for Physicians webpage on the CMS Web site at *http://www.cms.hhs.gov/CompetitiveAcquisforBios/02_infophys.asp#TopOfPage*.

Physicians who elect to participate in the CAP during the additional CY 2007 election period will have their CAP election agreement effective from August 1, 2007 through December 31, 2007. We note that participation in the CAP for CY 2008 requires renewal of CAP election during the regular fall