

Dated: May 16, 2007.

**Michelle Shortt,**

*Director, Regulations Development Group,  
Office of Strategic Operations and Regulatory  
Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10207]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to 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:* Physician Self-Referral Exceptions for Electronic Prescribing and Electronic Health Records (CMS-1303-F); *Form Number:* CMS-10207 (OMB#: 0938-1009); *Use:* Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) directs the Secretary to create an exception to the physician self-referral prohibition in section 1877 of the Act for certain arrangements in which a physician receives compensation in the form of items or services (not including cash or cash equivalents) ("nonmonetary remuneration") that is necessary and used solely to receive and transmit electronic prescription information. In addition, using our separate legal authority under section 1877(b)(4) of the Act, the regulation

CMS-1303-F (71 FR 45140) created a separate regulatory exception for certain arrangements involving the provision of nonmonetary remuneration in the form of electronic health records software or information technology and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records. These exceptions are consistent with the President's goal of achieving widespread adoption of interoperable electronic health records to improve the quality and efficiency of health care while maintaining the levels of security and privacy that consumers expect.

The conditions for both exceptions require that arrangements for the items and services provided must be set forth in a written agreement, be signed by the parties involved, specify the items or services being provided and the cost of those items or services, and cover all of the electronic prescribing and/or electronic health records technology to be provided by the donating entity. We have suggested that, instead of one master agreement that is updated with each new donation, the parties may choose to create a specific new contract and then reference other agreements or cross-reference a master list of agreements.

The requirements associated with the exception for electronic prescribing items and services are limited to donations made by hospitals to members of their medical staffs; by group practices to their physician members; and by PDP sponsors and MA organizations to prescribing physicians. The requirements associated with the exception for electronic health records software or information technology and training services include donations by entities furnishing DHS to physicians. The paperwork burden is the creation and execution of the written agreements. The burden associated with the written agreement requirement is the time and effort necessary for documentation of the agreement between the parties, including the signatures of the parties. *Frequency:* Recordkeeping and Reporting—On occasion; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 27,440; *Total Annual Responses:* 54,730; *Total Annual Hours:* 17,545.

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://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to

[Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received at the address below, no later than 5 p.m. on July 24, 2007.

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—B, Attention: William N. Parham, III, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: May 21, 2007.

**Michelle Shortt,**

*Director, Regulations Development Group,  
Office of Strategic Operations and Regulatory  
Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-1274-NC]

#### Medicare and Medicaid Programs; Announcement of Applications From Two 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 two hospitals' requests 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 for each hospital.

**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 July 24, 2007.

**ADDRESSES:** In commenting, please refer to file code CMS-1274-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-1274-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-1274-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-1274-C 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 the 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 procure 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

hospitals. We will then make a final determination on the waiver request and notify the hospitals 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), the following two hospitals are requesting waivers 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.

Institute for Orthopaedic Surgery is requesting a waiver to work with: LifeLine of Ohio, 770 Kinnear Road, Columbus, OH 43212.

Institute for Orthopaedic Surgery's Designated OPO is: LifeConnection of Ohio, 40 Wyoming Street, Dayton, OH 45409.

Trinity at Terrace Park Medical Center is requesting a waiver to work with: Iowa Donor Network, 550 Madison Avenue, North Liberty, IA 52317.

Trinity at Terrace Park Medical Center's designated OPO is: Gift of Hope Organ and Tissue Donor Network, 660 N. Industrial Drive, Elmhurst, IL 60126.

**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: May 11, 2007

**Leslie V. Norwalk,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 07-2441 Filed 5-18-07; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-3181-PN]

#### Medicare Program; Application by the American Diabetes Association (ADA) for Continued Recognition as a National Accreditation Program for Accrediting Entities To Furnish Outpatient Diabetes Self-Management Training

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

**ACTION:** Proposed notice.

**SUMMARY:** This proposed notice announces the receipt of an application from the American Diabetes Association (ADA) for continued recognition as a national accreditation program for accrediting entities that wish to furnish outpatient diabetes self-management training to Medicare beneficiaries. Section 1865(b)(3) of the Social Security Act (the Act) requires that we publish a notice identifying the national accreditation body making the request, describing the nature of the request, and providing at least a 30-day public comment period.

**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 June 25, 2007.

**ADDRESSES:** In commenting, please refer to file code CMS-3181-PN. 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-3181-PN, 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-3181-PN, 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:** Joan A. Brooks, (410) 786-5526.

#### 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-3181-PN 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.]

Under the Medicare program, eligible beneficiaries may receive outpatient diabetes self-management training when ordered by the physician or qualified non-physician practitioner treating the