

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Determination Concerning a Petition To Add a Class of Employees to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice of a determination concerning a petition to add a class of employees from the United Nuclear Corporation in Hematite, Missouri, to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA), 42 U.S.C. 7384q. On December 7, 2012, the Secretary of HHS determined that the following class of employees does not meet the statutory criteria for addition to the SEC as authorized under EEOICPA:

All site employees who worked in any area of the United Nuclear Corporation—Hematite, Missouri, site from January 1, 1958, through December 31, 1973, and the residual period January 1, 1974, through July 31, 2006.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, MS C-46, Cincinnati, OH 45226, Telephone 1-877-222-7570. Information requests can also be submitted by email to DCAS@CDC.GOV.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2012-31215 Filed 12-31-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice of Availability: Test Tools and Test Procedures Approved by the National Coordinator for the ONC HIT Certification Program

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This notice announces the availability of test tools and test procedures approved by the National Coordinator for Health Information

Technology (the National Coordinator) for the testing of EHR technology to the 2014 Edition EHR certification criteria under the ONC HIT Certification Program. The approved test tools and test procedures are identified on the ONC Web site at: <http://www.healthit.gov/policy-researchers-implementers/2014-edition-final-test-method>.

FOR FURTHER INFORMATION CONTACT:

Carol Bean, Director, Office of Certification, Office of the National Coordinator for Health Information Technology, 202-690-7151.

SUPPLEMENTARY INFORMATION: On January 7, 2011, the Department of Health and Human Services issued a final rule establishing a permanent certification program for the purposes of testing and certifying health information technology (“Establishment of the Permanent Certification Program for Health Information Technology,” 76 FR 1262) (Permanent Certification Program final rule). The permanent certification program was renamed the “ONC HIT Certification Program” in a final rule published on September 4, 2012 (77 FR 54163) (“2014 Edition EHR Certification Criteria final rule”). In the preamble of the Permanent Certification Program final rule, we stated that when the National Coordinator had approved test tools and test procedures for certification criteria adopted by the Secretary ONC would publish a notice of availability in the **Federal Register** and identify the approved test tools and test procedures on the ONC Web site. In the 2014 Edition EHR Certification Criteria final rule the Secretary adopted the 2014 Edition EHR certification criteria. The National Coordinator has approved test tools and test procedures for testing EHR technology to the 2014 Edition EHR certification criteria under the ONC HIT Certification Program. These approved test tools and test procedures are identified on the ONC Web site at: <http://www.healthit.gov/policy-researchers-implementers/2014-edition-final-test-method>.

Authority: 42 U.S.C. 300jj-11.

Dated: December 19, 2012.

Farzad Mostashari M.D.,
National Coordinator for Health Information Technology.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1456-NC]

Medicare and Medicaid Programs; Announcement of 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: A hospital has requested a waiver of statutory requirements that would otherwise require the hospital to enter into an agreement with its designated Organ Procurement Organization (OPO). The request was made 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 March 4, 2013.

ADDRESSES: In commenting, please refer to file code CMS-1456-NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the “More Search Options” tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1456-NC, P.O. Box 8010, Baltimore, MD 21244-1850.

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 to the following address ONLY: Department of Health and Human Services, Attention: CMS-1456-NC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses:

a. For delivery in Washington, DC—
Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey 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.)

b. For delivery in Baltimore, MD—
Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

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

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

FOR FURTHER INFORMATION CONTACT:
Patricia Taft, (410) 786–4561.

SUPPLEMENTARY INFORMATION: *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 comments received before the close of the comment period on the following web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions 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

Organ Procurement Organizations (OPOs) are not-for-profit organizations that are responsible for the procurement, preservation, and transport of 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, pursuant to section 371(b)(1) of the Public Health Service Act (42 U.S.C. 273(b)(1)) 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/or Medicaid are required to work with that OPO in providing organs for transplant, pursuant 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 only with its designated OPO to identify potential donors.

However, section 1138(a)(2)(A) of the Act provides that a hospital may obtain a waiver of the above 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)(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 assure 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 submit comments during the 60-day comment 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 § 486.308(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 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 comments received. During the review process, we may consult on an as-needed basis with the Health Resources and Services Administration’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

As permitted by § 486.308(e), the following hospital has requested a waiver to enter into an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located: Bolivar Medical Center in Cleveland, Mississippi, is requesting a waiver to work with: Mississippi Organ Recovery Agency, 4400 Lakeland Drive, Flowood, MS 39232.

The Hospital’s Designated OPO is: Mid-South Transplant Foundation, Inc., 8001 Centerview Parkway, Suite 302, Memphis, TN 38018.

(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: December 19, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2012-31535 Filed 12-31-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0523]

Guidance for Industry and Food and Drug Administration Staff; Refuse To Accept Policy for 510(k)s; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Refuse to Accept Policy for 510(k)s." The purpose of this document is to explain the procedures and criteria FDA intends to use in determining whether a 510(k) submission is administratively complete, which determines whether it should be accepted for substantive review and clearance. This guidance is applicable to 510(k)s reviewed in the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER).

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "Refuse to Accept Policy for 510(k)s" to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002; or Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the

Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Geeta Pamidimukkala, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1564, Silver Spring, MD 20993-0002, 301-796-6453; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of the 510(k) acceptance review is to make a threshold determination whether a submission is administratively complete, which determines whether it should be accepted for substantive review to reach a determination regarding substantial equivalence under section 513(i) of the FD&C Act, 21 U.S.C. 360c(i). To find a device substantially equivalent under section 513(i) of the FD&C Act, FDA must find that it has the same intended use as the predicate device, and either: (1) Has the same technological characteristics as the predicate device, or (2) has different technological characteristics, as defined at section 513(i)(1)(B), and (3) the submission contains information, including appropriate clinical or scientific data if necessary, that demonstrates the device is as safe and effective as the predicate and does not raise different questions of safety and effectiveness from the predicate.

The purpose of this document is to explain the procedures and criteria FDA intends to use in determining whether a 510(k) submission is administratively complete and should be accepted for substantive review. This guidance document provides updated information to two existing guidance documents entitled "Center for Devices and Radiological Health's Premarket Notification (510(k)) Refuse to Accept Policy" issued on June 30, 1993 and "510(k) Refuse to Accept Procedures, 510(k) Memorandum K94-1" issued on May 20, 1994. Upon issuance as a final guidance document, this guidance will replace those documents.

To further focus the Agency's review resources on complete applications, which will provide a more efficient approach to ensuring that safe and effective medical devices reach patients

as quickly as possible, we have modified the 1993 and 1994 guidances. For example, we have modified the 510(k) Refuse to Accept (RTA) policy to include an early review against specific acceptance criteria and to inform the submitter within the first 15 calendar days of receipt of the submission if the submission is administratively complete, or if not, to identify the missing element(s). In order to enhance the consistency of our acceptance decisions and to help submitters better understand the types of information FDA needs to conduct a substantive review, this guidance, including the checklists included in the appendices, clarifies the necessary elements and contents of a complete 510(k) submission. These elements are applicable to all devices reviewed through the 510(k) notification process in CDRH and CBER and have been compiled into checklists for use by FDA review staff.

In the **Federal Register** of August 13, 2012 (77 FR 48159), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by September 27, 2012. Eleven sets of comments were received with multiple recommendations pertaining to the administrative processes and policies regarding 510(k) acceptance decisions.

A number of commenters expressed concern that the checklist questions related to performance data implied that FDA staff would need to conduct a level of substantive review in order to complete the checklist. FDA has revised the language in these questions and added further instructions to FDA staff to more specifically state that only the presence of the information is required for acceptance, and that the adequacy of the information should only be assessed after acceptance and as part of the substantive review.

Similar comments were received regarding questions in the checklists that identified an "analysis" or "discussion" as a criterion for acceptance. Commenters were concerned that FDA staff would be assessing the adequacy of the "analysis" or "discussion" in order to complete the checklist. These questions have also been modified to explain more clearly that the acceptance criterion requires only that the "analysis" or "discussion" be present; the adequacy of this information should be assessed during the substantive review.

FDA received comments regarding relevant prior submissions and how prior FDA feedback relevant to determining substantial equivalence has been addressed in the submission under