

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 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, 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 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 to identify potential donors only with its designated OPO.

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 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 § 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 request and 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 Requests

As permitted by § 486.308(e), the following hospital 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:

Stafford Hospital (Medicare provider number 49-0140), of Stafford, Virginia, is requesting a waiver to work with:

LifeNet Health, 1864 Concert Drive, Virginia Beach, VA 23453.

The Hospital's Designated OPO is: Washington Regional Transplant Consortium, 7619 Little River Turnpike, Suite 900, Annandale, VA 22002.

## IV. 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 (44 U.S.C. 35).

(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: July 15, 2010.

**Marilyn Tavenner,**

*Principal Deputy Administrator and Chief Operating Officer, Centers for Medicare & Medicaid Services.*

[FR Doc. 2010-18137 Filed 7-22-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-5047-N]

### Medicare Program; Solicitation for Proposals for the Medicare Imaging Demonstration

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

**ACTION:** Notice.

**SUMMARY:** This notice informs interested parties (here in there after referred to as conveners) of an opportunity to apply to participate in the Medicare Imaging Demonstration (MID) that was authorized by section 135(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). The goal of the MID is to collect data regarding physician compliance with appropriateness criteria selected by the Secretary under the terms of the statute in order to determine the appropriateness of advanced diagnostic imaging services furnished to Medicare beneficiaries.

**DATES:** Proposals will be considered timely if they are received on or before 5 p.m., Eastern Standard Time (E.S.T.) on September 21, 2010.

**ADDRESSES:** Proposals should be mailed to the following address: Centers for Medicare & Medicaid Services, Attention: Linda R. Lebovic, 7500 Security Boulevard, Mail Stop: C4-17-27, Baltimore, Maryland 21244-1850.

**FOR FURTHER INFORMATION CONTACT:** Linda R. Lebovic at (410) 786-3402 or by e-mail at [ImagingDemo135b@cms.hhs.gov](mailto:ImagingDemo135b@cms.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

*General Information:* Please refer to file code [CMS-5047-N] on the application. Proposals (an unbound original and 3 copies plus an electronic copy on CD-ROM) must be typed for clarity and should not exceed 40 double-spaced pages, exclusive of cover letter, the executive summary, resumes, forms, and supporting documentation. Because of staffing and resource limitations, we cannot accept proposals by facsimile (FAX) transmission. Applicants may, but are not required to, submit a total of 10 copies to assure that each reviewer receives a proposal in the manner intended by the applicant (for example, collated, tabulated color copies). Hard copies and electronic copies must be identical.

*Eligible Organizations:* CMS anticipates that a wide variety of interested parties may be eligible to apply as conveners or in collaboration with other organizations to perform the responsibilities specified. Examples of conveners include, but are not limited to, medical specialty societies, physician groups, integrated health care delivery systems, independent practice associations, radiology benefit managers, health plans, information technology vendors, and collaborations among the above parties.

**I. Provisions of This Notice**

This notice informs interested parties (here in there after referred to as conveners) of an opportunity to apply to participate in the Medicare Imaging Demonstration (MID) that was authorized by section 135(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). The goal of the MID is to collect data regarding physician compliance with appropriateness criteria selected by the Secretary under the terms of the statute in order to determine the appropriateness of advanced diagnostic imaging services furnished to Medicare beneficiaries. The authorizing legislation allows the Secretary to include in the demonstration advanced diagnostic imaging services such as those defined in § 1834(e)(1)(B) of the Social Security Act (the Act): Diagnostic magnetic resonance imaging (MRI),

computed tomography (CT), nuclear medicine (including positron emission tomography) and such other diagnostic imaging services, including services described in § 1848(b)(4)(B) of the Act (excluding X-ray, ultrasound, and fluoroscopy), as specified by the Secretary in consultation with physician specialty organizations and other stakeholders. The law requires that the appropriateness criteria used in the demonstration be based on those developed or endorsed by medical specialty societies. The Centers for Medicare & Medicaid Services (CMS) worked with medical specialty societies and other stakeholders, including the AQA Alliance, to get their input and information on available appropriateness criteria. For purposes of this demonstration, the "appropriateness criteria" referenced in the statute will be published medical specialty society guidelines relevant to the 11 procedures studied in the demonstration that are developed or endorsed by relevant medical specialty societies, are consistent with the spirit of section 135(b)(2)(B)(ii)(II), and which have been selected by the Secretary under the terms of the statute. (We believe the appropriateness criteria are the product of consensus and meet the spirit of section 135(b)(2)(B)(ii)(II) of MIPPA. Consequently, published medical specialty society guidelines relevant for the 11 procedures are included in the demonstration.

The law prohibits the use of prior authorization in the demonstration. The design of the demonstration will permit evaluation of the appropriateness of imaging services across a range of advanced diagnostic imaging studies, geographic areas, demographic characteristics and practice settings (such as private and academic practices) in the Medicare fee-for-service program. CMS is seeking participation by 2,500 to 3,500 physicians from 500 to 650 physician practices that vary in size, specialty mix, type (academic and private practice), and location (urban, rural, and suburban) to obtain substantial sample size for the evaluation.

The demonstration will test whether the use of decision support systems (DSSs) can improve quality of care and reduce unnecessary radiation exposure and utilization by promoting appropriate ordering of advanced diagnostic imaging services. Physician practices will receive feedback on the degree of appropriateness relative to the specified medical specialty society guidelines used under the demonstration.

CMS is seeking conveners that can provide a panel of participating physician practices that agree to use an advanced diagnostic imaging DSS for purposes of this demonstration. The Secretary has chosen to use conveners as a vehicle to recruit physician practices for participation in the demonstration because it is expected that the likely applicants for the convener have well developed relationships (or the ability to establish) with a significant network of physicians that could be potential applicants for participation in the demonstration. Therefore, conveners would be highly effective at providing a robust panel of physicians that could satisfy the selection requirements outlined in the statute. The convener will secure a DSS for advanced diagnostic imaging services that will remain current with the medical specialty society guidelines used under the demonstration, recruit physician practices, and make the DSS available to physician practices participating in the demonstration. Through the DSS, a convener will collect data on physician ordering of the specified services and test results, and provide feedback to physicians on ordering appropriateness. The convener will also distribute payments (as determined by CMS) to the participating practices for reporting data. In this capacity, the convener will be responding to the solicitation on its behalf as applicant. For the demonstration, interested parties may need to collaborate as a convener in order to have a panel of participating physician practices, the availability of the DSS for use by the physician practices, and must comply with demonstration requirements.

A competitive process will be used to select conveners. CMS anticipates selecting up to six conveners to participate in the 2-year demonstration. CMS is aware that certain arrangements under this demonstration could raise possible fraud, waste, and abuse concerns, including concerns under the anti-kickback statute and the physician self-referral law. While CMS has the authority to waive the application of certain fraud, waste, and abuse laws, it is anticipated that doing so, if at all, will only occur after evaluating the provisions of the proposals on a case-by-case basis and considering whether a waiver is necessary to carry out the demonstration project.

Physician practices must apply through a convener and the convener's application must include the criteria and rationale for recruiting physician practices and obtaining their buy-in for the use of the DSS. The Secretary has

chosen to use conveners as a vehicle to recruit physician practices for participation in the demonstration because it is expected that the likely applicants for the convenue have well developed relationships (or the ability to establish) with a significant network of physicians that could be potential applicants for participation in the demonstration. Therefore, conveners would be highly effective at providing a robust panel of physicians that could satisfy the selection requirements outlined in the statute. Conveners must also disclose in the application whether the DSS may be retained by the participating practice after the demonstration is concluded and whether the DSS may be used to order items and services other than the subject imaging services.

Applicants must submit their applications in the standard format outlined in CMS' Medicare Waiver Demonstration Application and MID solicitation in order to be considered for review by the technical review panel. Applications not received in this format will not be considered for review.

The Medicare Waiver Demonstration Application can be found electronically at: <http://www.cms.hhs.gov/cmsforms/downloads/cms10069.pdf>.

For specific details regarding the MID, please refer to the solicitation on the CMS Web site at: [http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/Medicare\\_Imaging\\_Demonstration.pdf](http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/Medicare_Imaging_Demonstration.pdf).

## II. Collection of Information Requirements

Section 135(b)(4)(A) of the MIPPA (Pub. L. 110–275) exempts this demonstration from the Chapter 35 of Title 44 of the United States Code; however, the collection form entitled “Medicare Demonstration Waiver Application” is currently approved under OMB control number 0938–0880.

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

Dated: April 1, 2010.

**Charlene Frizzera,**

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

[FR Doc. 2010–18139 Filed 7–22–10; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of General Medical Sciences Special Emphasis Panel, Research Centers in Trauma, Burn, and Peri-Operative Injury (P50).

*Date:* August 17, 2010.

*Time:* 1 p.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Natcher Building, 45 Center Drive, Room 3AN12B, Bethesda, MD 20892.

*Contact Person:* Margaret J. Weidman, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN18B, Bethesda, MD 20892, 301–594–3663, [weidmanma@mail.nih.gov](mailto:weidmanma@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: July 19, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010–18088 Filed 7–22–10; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Advisory Board on Radiation and Worker Health (ABRWH or Advisory Board), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), and pursuant to the requirements of 42 CFR 83.15(a), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee:

*Board Public Meeting Times and Dates (All times are Eastern Time):*

8:15 a.m.–3 p.m., August 10, 2010.

8:15 a.m.–4:15 p.m., August 11, 2010.

8:15 a.m.–12 p.m., August 12, 2010.

*Public Comment Times and Dates (All times are Eastern Time):*

3:30 p.m.–5 p.m.,\* August 10, 2010.

4:30 p.m.–6 p.m.,\* August 11, 2010.

\* Please note that the public comment periods may end before the times indicated, following the last call for comments. Members of the public who wish to provide public comment should plan to attend public comment sessions at the start times listed.

*Place:* Shilo Inn Suites Hotel, 780 Lindsay Blvd., Idaho Falls, Idaho; Phone: 208–523–0088; Fax: 208–522–7420. Audio Conference Call via FTS Conferencing. The USA toll free dial in number is 1–866–659–0537 with a pass code of 9933701.

*Status:* Open to the public, limited only by the space available. The meeting space accommodates approximately 150 people.

*Background:* The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program (EEOICP) Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines which have been promulgated by the Department of Health and Human Services (HHS) as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program, and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, and will expire on August 3, 2011.

*Purpose:* This Advisory Board is charged with (a) Providing advice to the Secretary,