

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled “2014 Scientific Meeting of the National Antimicrobial Resistance Monitoring System.” The purpose of the meeting is to discuss progress made in achieving the goals of the National Antimicrobial Resistance Monitoring System (NARMS) Strategic Plan: 2012–2016.

Dates And Time: The public meeting will be held on August 12 and 13, 2014, from 8 a.m. to 5 p.m.

ADDRESSES: *Location:* The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31, Great Room (rm. 1503A), Silver Spring, MD 20993–0002. Please note that visitors to the White Oak Campus must enter through Building 1. The White Oak Campus location is a Federal facility with security procedures. For parking and security information, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

FOR FURTHER INFORMATION CONTACT: Laura Bradbard, Center for Veterinary Medicine (HFV–12), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9109, FAX: 240–276–9115, laura.bradbard@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: NARMS periodically conducts public meetings to inform stakeholders of NARMS activities and receive comments on ways to improve. The last two public NARMS meetings (held in 2010 and 2011) focused on recommendations made by the FDA Science Board Advisory Subcommittee in 2007. These meetings dealt with enhancing international partnerships, and improving NARMS sampling. Since then, NARMS created the 2012–2016 Strategic Plan that addressed all of the Science Board’s recommendations (<http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/UCM236283.pdf>). A number of strategic planning goals already have been achieved and several of the objectives outlined in the plan are ongoing. The purpose of this meeting will be to provide updates on progress of the NARMS 2012–2016 strategic plan, discuss possible future activities, and receive comments for the official record. A number of items will be discussed including comparisons of new and old slaughter sampling

methods, the role of NARMS in foodborne outbreaks, results of interagency research projects using advanced detection methods, and how these scientific advances impact FDA decisionmaking.

Registration and Requests for Oral Presentations: Interested persons may make oral presentations on the topic of the discussion of the meeting. Oral presentations from the public during the open public comment period will be scheduled between approximately 3:50 p.m. and 4:50 p.m. on August 13, 2014. Those desiring to make oral presentations should notify the contact person by July 29, 2014, and submit a brief statement of the general nature of information they wish to present. In an effort to accommodate all who desire to speak, time allotted for each presentation may be limited. The contact person will inform each speaker of their schedule prior to the meeting.

Registration is required for the meeting. Please send registration information (including name, title, organization, address, and telephone and fax numbers) by email to Laura Bradbard (see **FOR FURTHER INFORMATION CONTACT**) by July 29, 2014. There is no fee to register for the public meeting, and registration will be on a first-come, first-served basis.

If you need special accommodations due to a disability, please contact Laura Bradbard (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

Comments: Regardless of attendance at the public meeting, interested persons may submit either electronic or written comments regarding the topic to be discussed at the meeting. Submit electronic comments 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. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. The docket will remain open for written or electronic comments for 30 days following the meeting.

Agenda: The meeting will address monitoring and research for NARMS. The final agenda for the public meeting will be made available on the Agency’s Web site at <http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/ucm059135.htm> and will be posted to the docket

at <http://www.regulations.gov> no later than 2 weeks prior to the meeting.

Transcripts: FDA will prepare a meeting transcript and make it available on the Agency’s Web site (see *Agenda*) after the meeting. FDA anticipates that transcripts will be available approximately 60 business days after the meeting. The transcript will be available for public examination at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. A transcript will also be available in either hardcopy or on CD-ROM after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: July 7, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Solicitation of Information and Recommendations for Revising OIG’s Non-Binding Criteria for Implementing Permissive Exclusion Authority Under Section 1128(b)(7) of the Social Security Act

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice and Opportunity for Comment.

SUMMARY: This **Federal Register** notice informs the public that OIG: (1) Is considering revising the Non-Binding Criteria for Implementing Permissive Exclusion Authority Under Section 1128(b)(7) of the Social Security Act (62 FR 67392, December 24, 1997), and (2) is soliciting input from the public for OIG to consider in developing the revised criteria.

DATES: To ensure consideration, public comments must be delivered to the address provided below by no later than 5 p.m. on September 9, 2014.

ADDRESSES: In commenting, please refer to file code OIG–1271–N. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. *Electronically.* You may submit electronic comments on specific recommendations and proposals through the Federal eRulemaking Portal at <http://www.regulations.gov>.

2. *By regular, express, or overnight mail.* You may send written comments to the following address: Patrice Drew, Office of Inspector General, Department of Health and Human Services, Attention: OIG-1271-N, Room 5296, Cohen Building, 330 Independence Avenue SW., Washington, DC 20201. Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver, by hand or courier, your written comments before the close of the comment period to Patrice Drew, Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue SW., Washington, DC 20201. Because access to the interior of the Cohen Building is not readily available to persons without Federal Government identification, commenters are encouraged to schedule their delivery with one of our staff members at (202) 619-1368.

For information on viewing public comments, please see the Supplementary Information section.

FOR FURTHER INFORMATION CONTACT: Patrice Drew, Department of Health and Human Services, Office of Inspector General, Office of External Affairs, at (202) 619-1368.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the end of the comment period are available for viewing by the public. All comments will be posted on <http://www.regulations.gov> as soon as possible after the closing of the comment period. Comments received timely will also be available for public inspection as they are received at Office of Inspector General, Department of Health and Human Services, Cohen Building, 330 Independence Avenue SW., Washington, DC 20201, Monday through Friday of each week from 10 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (202) 619-1368.

Background

Section 1128(b)(7) of the Social Security Act (Act) authorizes the Secretary, and by delegation the Inspector General, to exclude an individual or entity from participation in the Federal health care programs for engaging in conduct described in sections 1128A and 1128B of the Act. In

general, OIG may seek to exclude any person who violates the Federal False Claims Act, 31 U.S.C. 3729-3733, or the Civil Monetary Penalties Law, section 1128A of the Act. For example, submitting or causing the submission of false or fraudulent claims or soliciting or paying kickbacks in violation of the Federal Anti-Kickback Statute, section 1128B of the Act, can result in exclusion from participation in Medicare, Medicaid, and all other Federal health care programs. On October 24, 1997, OIG published a proposed policy statement in the **Federal Register** (62 FR 55410) in the form of non-binding criteria to be used by OIG in assessing whether to impose a permissive exclusion under section 1128(b)(7) of the Act. On December 24, 1997, OIG published the final policy statement in the **Federal Register** (62 FR 67392).

Since 1997, OIG has used these criteria to evaluate whether to impose a permissive exclusion under section 1128(b)(7) of the Act or release this authority in exchange for the defendant's entering into an Integrity Agreement with OIG. On the basis of our experience evaluating permissive exclusion in False Claims Act and administrative cases over the past 17 years, we are considering revising the existing criteria. We believe revised criteria may help the provider community understand how OIG exercises its discretion in cases under section 1128(b)(7) of the Act. We also believe that updated guidance could better reflect the state of the health care industry today, including the changes in legal requirements and the emergence of the health care compliance industry.

In considering possible revisions to the criteria, we are soliciting comments, recommendations, and other suggestions from concerned parties on how best to revise the criteria to address relevant issues and to provide useful guidance to the health care industry. The issues we are considering include, but are not limited to: (1) Whether there should be differences in the criteria for individuals and entities and (2) whether and how to consider a defendant's existing compliance program.

After reviewing any timely submitted comments, we will decide whether and how to revise the non-binding criteria for use in evaluating exclusion under 1128(b)(7) of the Act where the defendant has defrauded the Federal health care programs.

Dated: June 7, 2014.

Daniel R. Levinson,
Inspector General.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Special Fraud Alert: Laboratory Payments to Referring Physicians

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This Special Fraud Alert addresses compensation paid by laboratories to referring physicians and physician group practices (collectively, physicians) for blood specimen collection, processing, and packaging, and for submitting patient data to a registry or database. OIG has issued a number of guidance documents and advisory opinions addressing the general subject of remuneration offered and paid by laboratories to referring physicians, including the 1994 Special Fraud Alert on Arrangements for the Provision of Clinical Laboratory Services, the OIG Compliance Program Guidance for Clinical Laboratories, and Advisory Opinion 05-08. In these and other documents, we have repeatedly emphasized that providing free or below-market goods or services to a physician who is a source of referrals, or paying such a physician more than fair market value for his or her services, could constitute illegal remuneration under the anti-kickback statute. This Special Fraud Alert supplements these prior guidance documents and advisory opinions and describes two specific trends OIG has identified involving transfers of value from laboratories to physicians that we believe present a substantial risk of fraud and abuse under the anti-kickback statute.

I. The Anti-Kickback Statute

One purpose of the anti-kickback statute is to protect patients from inappropriate medical referrals or recommendations by health care professionals who may be unduly influenced by financial incentives. Section 1128B(b) of the Social Security Act (the Act) makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, referrals of items or services reimbursable by a Federal health care program. When remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. Violation of the statute constitutes a felony punishable