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.

[FR Doc. 2014–16222 Filed 7–10–14; 8:45 am]

BILLING CODE 4150–04–P

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

by a maximum fine of $25,000, imprisonment up to 5 years, or both. Conviction will also lead to exclusion from Federal health care programs, including Medicare and Medicaid. OIG may also initiate administrative proceedings to exclude persons from the Federal health care programs or to impose civil money penalties for fraud, kickbacks, and other prohibited activities under sections 1128(b)(7) and 1128A(a)(7) of the Act.

II. Remuneration From Laboratories To Referring Physicians

Arrangements between referring physicians and laboratories historically have been subject to abuse and were the topic of one of the OIG's earliest Special Fraud Alerts.[1] In that Special Fraud Alert, we stated that, ''[w]henever a laboratory offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the thing of value is offered to induce the referral of business.'' More generally, we have, on various occasions, repeated our position that arrangements providing free or below-market goods or services to actual or potential referral sources are suspect and may violate the anti-kickback statute, depending on the circumstances.[2]

Likewise, when a laboratory pays a physician more than fair market value for the physician's services or for services the laboratory does not actually need or for which the physician is otherwise compensated, the anti-kickback statute is implicated. Such payments are suspect under the anti-kickback statute because of the implication that one purpose of the payments is to induce the physician's Federal health care program referrals. OIG also historically has been concerned with arrangements in which the amounts paid to a referral source take into account the volume or value of business generated by the referral source.

Arrangements in which laboratories provide free or below-market goods or services to physicians or make payments to physicians that are not commercially reasonable in the absence of Federal health care program referrals potentially raise four major concerns typically associated with kickbacks—corruption of medical judgment, overutilization, increased costs to the Federal health care programs and beneficiaries, and unfair competition. This is because such transfers of value may induce physicians to order tests from a laboratory that provides them with remuneration, rather than the laboratory that provides the best, most clinically appropriate service. Such transfers of value also may induce physicians to order more laboratory tests than are medically necessary, particularly when the transfers of value are tied to, or take into account, the volume or value of business generated by the physician. We are particularly concerned about these types of arrangements because the choice of laboratory, as well as the decision to order laboratory tests, typically is made or strongly influenced by the physician, with little or no input from patients.

Although physicians may order any tests they believe are appropriate to diagnose and treat their patients, Medicare will pay for laboratory tests only if they meet Medicare coverage criteria and are reasonable and necessary.[3] Moreover, claims that include items or services resulting from a violation of the anti-kickback statute are not payable by Medicare and may constitute false claims under the False Claims Act, even if the items or services are medically necessary.[4] OIG recognizes that the lawfulness of any particular arrangement under the anti-kickback statute depends on the intent of the parties. Such intent may be evidenced by the arrangement's characteristics, including its legal structure, its operational safeguards, and the actual conduct of the parties to the arrangement. Nonetheless, we believe the following types of arrangements between laboratories and physicians are suspect under the anti-kickback statute.

A. Blood-Specimen Collection, Processing, and Packaging Arrangements

OIG has become aware of arrangements under which clinical laboratories are providing remuneration to physicians to collect, process, and package patients' specimens. This Special Fraud Alert addresses arrangements under which laboratories pay physicians, either directly or indirectly (such as through an arrangement with a marketing or other agent) to collect, process, and package patients' blood specimens (Specimen Processing Arrangements).[5] Specimen Processing Arrangements typically involve payments from laboratories to physicians for certain specified duties, which may include collecting the blood specimens, centrifuging the specimens, maintaining the specimens at a particular temperature, and packaging the specimens so that they are not damaged in transport. Payments under Specimen Processing Arrangements typically are made on a per-specimen or per-patient-encounter basis and often are associated with expensive or specialized tests.

Medicare allows the person who collects a specimen to bill Medicare for a nominal specimen collection fee in certain circumstances, including times when the person draws a blood sample through venipuncture (*i.e.,* inserting into a vein a needle with syringe or vacuum tube to draw the specimen).[6] Medicare allows such billing only when: (1) It is the accepted and prevailing practice among physicians in the locality to make separate charges for drawing or collecting a specimen and (2) it is the customary practice of the physician performing such services to bill separate charges for drawing or collecting the specimen.[7] Only one collection fee is allowed for each type of specimen for each patient encounter, regardless of the number of specimens drawn.[8] Physicians who satisfy the specimen collection fee criteria and choose to bill Medicare for the specimen collection must use Current Procedural Terminology (CPT) Code 36415, ''Routine venipuncture—Collection of venous blood by venipuncture.'' [9] [10]

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[1] Special Fraud Alert: Arrangements for the Provision of Clinical Laboratory Services (Oct. 1994), *reprinted at* 59 FR 65,372, 65,377 (Dec. 19, 1994).

[2] *See, e.g.,* Advisory Opinion 11–07, p. 7.

[3] Section 1862(a)(1)(A) of the Act.

[4] 31 U.S.C. 3729 et seq.

[5] The same principles described in this Special Fraud Alert apply to arrangements that are similar or analogous to Specimen Processing Arrangements, including arrangements under which clinical laboratories pay physicians to collect and package patients' buccal swabs or urine specimens or provide free or below-market point of care urine testing cups to health care providers who use the cups to perform billable in-office testing.

[6] Section 1833(h)(3) of the Act; *Medicare Claims Processing Manual,* CMS Pub. 100–04, Chapter 16, section 60.1.

[7] *Medicare Claims Processing Manual,* CMS Pub. 100–04, Chapter 16, section 60.1.1.

[8] *Medicare Claims Processing Manual,* CMS Pub. 100–04, Chapter 16, section 60.1.

[9] The five character codes and descriptions included in this document are obtained from Current Procedural Terminology (CPT®), copyright 2014 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures. Any use of CPT outside of this document should refer to the most current version of the Current Procedural Terminology available from AMA. Applicable FARS/DFARS apply.

[10] CPT code 36415 is included on the clinical laboratory fee schedule. As of the date of issuance of this Special Fraud Alert, Medicare pays a specimen collection fee of $5 for samples collected from individuals in skilled nursing facilities and by laboratories on behalf of home health agencies and a specimen collection fee of $3 for all other samples. *See, e.g.,* Clinical Laboratory Fee Schedule—January 2014 Release, *available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/*

Medicare reimburses physicians for processing and packaging specimens for transport to a clinical laboratory through a bundled payment.[11] Physicians who wish to report the work involved in preparing a specimen to send to a laboratory may use CPT code 99000, ''Handling and/or conveyance of specimen for transfer from the office to a laboratory.'' [12] CPT code 99000 is intended to reflect the work involved to prepare a specimen prior to sending it to a laboratory, including centrifuging a specimen, separating serum, labeling tubes, packing the specimens for transport, filling out laboratory forms, and supplying necessary insurance information and other documentation.[13]

The anti-kickback statute is implicated when a clinical laboratory pays a physician for services. Whether an actual violation of the statute occurs depends on the intent of the parties—the anti-kickback statute prohibits the knowing and willful payment of such amounts if even one purpose of the payment is to induce or reward referrals of Federal health care program business. This is true regardless of whether the payment is fair market value for services rendered. The probability that a payment is for an illegitimate purpose is increased, however, if a payment exceeds fair market value or if it is for a service for which the physician is paid by a third party, including Medicare.

When determining the fair market value of a physician's services, a clinical laboratory should consider whether the services for which it may compensate the physician have been, or may be, paid for, including through a bundled payment, by Medicare. Additionally, the laboratory should consider whether payment is appropriate at all; if the services for which the laboratory intends to compensate the physician are paid for by a third party through other means, such as payments intended to reimburse the physician for overhead expenses, any payment by the laboratory to the physician may constitute double payment for the physician's services and, consequently, provide evidence of unlawful intent.

Characteristics of a Specimen Processing Arrangement that may be evidence of such unlawful purpose include, but are not limited to, the following:

- Payment exceeds fair market value for services actually rendered by the party receiving the payment.
- Payment is for services for which payment is also made by a third party, such as Medicare.
- Payment is made directly to the ordering physician rather than to the ordering physician's group practice, which may bear the cost of collecting and processing the specimen.
- Payment is made on a per-specimen basis for more than one specimen collected during a single patient encounter or on a per-test, per-patient, or other basis that takes into account the volume or value of referrals.
- Payment is offered on the condition that the physician order either a specified volume or type of tests or test panel, especially if the panel includes duplicative tests (*e.g.,* two or more tests performed using different methodologies that are intended to provide the same clinical information), or tests that otherwise are not reasonable and necessary or reimbursable.
- Payment is made to the physician or the physician's group practice, despite the fact that the specimen processing is actually being performed by a phlebotomist placed in the physician's office by the laboratory or a third party.

OIG's concerns regarding Specimen Processing Arrangements are not abated when those arrangements apply only to specimens collected from non-Federal health care program patients. Arrangements that ''carve out'' Federal health care program beneficiaries or business from otherwise questionable arrangements implicate the anti-kickback statute and may violate it by disguising remuneration for Federal health care program business through the payment of amounts purportedly related to non-Federal health care program business. Because physicians typically wish to minimize the number of laboratories to which they refer for reasons of convenience and administrative efficiency, Specimen Processing Arrangements that carve out Federal health care program business may nevertheless be intended to influence physicians' referrals of Federal health care program business to the offering laboratories.

Finally, because the anti-kickback statute ascribes criminal liability to parties on both sides of an impermissible ''kickback'' arrangement, physicians who enter into Specimen Processing Arrangements with laboratories also may be at risk under the statute.

B. Registry Payments

OIG has become aware of arrangements under which clinical laboratories are establishing, coordinating, or maintaining databases, either directly or through an agent, purportedly to collect data on the demographics, presentation, diagnosis, treatment, outcomes, or other attributes of patients who have undergone, or who may undergo, certain tests performed by the offering laboratories. Typically these are specialized and expensive tests paid for by Federal health care programs. This Special Fraud Alert addresses such ''Registries'' or ''Registry Arrangements,'' whether they are referred to as ''registries'' or ''observational outcomes databases'' or by other terminology.

Laboratories that participate in Registry Arrangements often assert that they are intended to advance clinical research to promote treatment, to provide physicians with valuable clinical knowledge for patients with similar disease profiles, and to provide other benefits to physicians or the health care industry generally. Registry Arrangements may take various forms; however, they typically involve payments from laboratories to physicians for certain specified duties, including, by way of example only, submitting patient data to be incorporated into the Registry, answering patient questions about the Registry, and reviewing Registry reports.

Registry Arrangements may induce physicians to order medically unnecessary or duplicative tests, including duplicative tests performed for the purpose of obtaining comparative data, and to order those tests from laboratories that offer Registry

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clinlab.html; specifically CLAB2014.EffJan1.Full.xlsx (the 2014 Clinical Diagnostic Laboratory Fee Schedule), *available at http://www.cms.gov/apps/ama/license.asp?file=/ClinicalLabFeeSched/downloads/14CLAB.zip*; and Protecting Access to Medicare Act of 2014, Public Law 113–93, § 216(a), 128 Stat. 1040 and 1053–1059 (to be codified at 42 U.S.C. 1395m–1(b)(5)) (2014).

[11] Since 2003, CPT code 99000 has been listed as a ''Bundled Code'' in the Medicare Physician Fee Schedule (MPFS). *See, e.g.,* Physician Fee Schedule—January 2014 Release, *available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files-Items/RVU14A.html*; *specifically* PPRRVU14_V1219.xlsx (the 2014 National Physician Fee Schedule Relative Value File) and RVUPUF14.pdf (containing information on services covered by the MPFS, including fee schedule status indicators), *available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/RVU14A.zip.* A ''Bundled Code'' means that ''[p]ayment for covered services are always bundled into payment for other services not specified.'' RVUPUF14.pdf, Attachment A.

[12] Even though physicians are not directly reimbursed under this code, as they are with CPT code 36145, they may choose to report this CPT code so that the costs associated with the services they perform are taken into account in CMS's calculation of the practice expense component of a procedure's relative value unit. *See* Overview, MPFS, *available at https://www.cms.gov/apps/physician-fee-schedule/overview.aspx.*

[13] *Coding Clarification: Handling and/or Conveyance of Specimen for Transfer from the Physician's Office to a Laboratory,* CPT Assistant (AMA), Oct. 1999, at 11.

Arrangements in lieu of other, potentially clinically superior, laboratories. OIG recognizes that whether any particular Registry Arrangement violates the anti-kickback statute depends on the intent of the parties to the arrangement. Payments from a laboratory to a physician to compensate the physician for services related to data collection and reporting may be reasonable in certain limited circumstances. However, the anti-kickback statute prohibits the knowing and willful payment of such compensation if even one purpose of the payments is to induce or reward referrals of Federal health care program business.

Characteristics of a Registry Arrangement that may be evidence of such unlawful purpose include, but are not limited to, the following:

- The laboratory requires, encourages, or recommends that physicians who enter into Registry Arrangements perform the tests with a stated frequency (*e.g.,* four times per year) to be eligible to receive, or to not receive a reduction in, compensation.
- The laboratory collects comparative data for the Registry from, and bills for, multiple tests that may be duplicative (*e.g.,* two or more tests performed using different methodologies that are intended to provide the same clinical information) or that otherwise are not reasonable and necessary.
- Compensation paid to physicians pursuant to Registry Arrangements is on a per-patient or other basis that takes into account the value or volume of referrals.
- Compensation paid to physicians pursuant to Registry Arrangements is not fair market value for the physicians' efforts in collecting and reporting patient data.
- Compensation paid to physicians pursuant to Registry Arrangements is not supported by documentation, submitted by the physicians in a timely manner, memorializing the physicians' efforts.
- The laboratory offers Registry Arrangements only for tests (or disease states associated with tests) for which it has obtained patents or that it exclusively performs.
- When a test is performed by multiple laboratories, the laboratory collects data only from the tests it performs.
- The tests associated with the Registry Arrangement are presented on the offering laboratory's requisition in a manner that makes it more difficult for the ordering physician to make an independent medical necessity decision with regard to each test for which the laboratory will bill (*e.g.,* disease-related panels).

Other characteristics not listed above may increase the risk of fraud and abuse associated with a Registry Arrangement or provide evidence of unlawful intent. For example, the risk of fraud and abuse would be particularly high if a laboratory were to pay, and collect data for its Registry from, only a subset of physicians who were selected on the basis of their prior or anticipated referral volume, rather than their specialty, sub-specialty, or other relevant attribute.

The anti-kickback statute does not prohibit laboratories from engaging in, or paying compensation for, legitimate research activities. However, claims that Registries are intended to promote and support clinical research and treatment are not sufficient to disprove unlawful intent. Even legitimate actions taken to substantiate such claims, including, for example, retaining an independent Institutional Review Board to develop study protocols and participation guidelines, will not protect a Registry Arrangement if one purpose of the arrangement is to induce or reward referrals. Furthermore, for the reasons set forth in section II.A above, OIG's concerns regarding Registry Arrangements are not abated when those arrangements apply only to data collected from tests performed on non-Federal health care program patients' specimens.

Finally, because the anti-kickback statute ascribes criminal liability to parties on both sides of an impermissible ''kickback'' arrangement, physicians who enter into Registry Arrangements with laboratories also may be at risk under the statute.

III. Conclusion

OIG is concerned about the risks that Specimen Processing Arrangements and Registry Arrangements pose under the anti-kickback statute. This Special Fraud Alert reiterates our longstanding concerns about payments from laboratories to physicians in excess of the fair market value of the physicians' services and payments that reflect the volume or value of referrals of Federal health care program business. Should interested parties continue to have questions about the structure of a particular Specimen Processing Arrangement or Registry Arrangement, the OIG Advisory Opinion process remains available. Information about the process may be found at: *http://oig.hhs.gov/faqs/advisory-opinions-faq.asp.*

To report suspected fraud involving Registry Arrangements, Specimen Processing Arrangements, or similar arrangements, contact the OIG Hotline at *https://forms.oig.hhs.gov/hotlineoperations/or* by phone at 1–800–447–8477 (1–800–HHS–TIPS).

Dated: June 7, 2014.

Daniel R. Levinson,

Inspector General.

[FR Doc. 2014–16219 Filed 7–10–14; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Evaluation Option Exclusive License: Development of Granulysin Immunotherapy

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive evaluation option license to practice the inventions embodied in U.S. Provisional Patent Application. No. 61/250,601, filed October 12, 2009, HHS Ref. No.: E–158–2009/0–US–01, Titled: ''Granulysin Immunotherapy''; International Application No. PCT/US2010/052036, filed October 8, 2010, HHS Ref. No.: E–158–2009/0–PCT–02, Titled: ''Granulysin Immunotherapy''; U.S. Patent Application No. 13/501,726, filed April 12, 2012, HHS Ref. No.: E–158–2009/0–US–06, Titled: ''Granulysin Immunotherapy'', and foreign equivalents thereof to Orpheden Therapeutics, Inc. (''Orpheden''), a Delaware corporation doing business principally in the state of Illinois. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive evaluation option license territory may be worldwide and the field of use may be limited to the development of 15kD granulysin as set forth in the Licensed Patent Rights for the treatment of human cancers.

Upon the expiration or termination of the exclusive evaluation option license, Orpheden will have the exclusive right to execute an exclusive commercialization license which will supersede and replace the exclusive evaluation option license with no greater field of use and territory than granted in the exclusive evaluation option license.