WASHINGTON G–2 REPORTS

NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

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Vol. 10, Iss. 18, October 8, 2010

Medicare Creates New Way to Resolve Self-Referral Violations

The self-disclosure protocol is at http://www.cms.gov/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf.

If you identify an actual or potential violation of the law governing physician self-referrals for designated health services payable by Medicare or Medicaid, you have a new avenue under Medicare to come forward to resolve any overpayment liability.

If you step forward, you may be able to reduce the stiff penalties set under the law, as long as in making the disclosure you intend to resolve liability for the conduct identified.

Several factors would be considered, including the nature of the violation, the timeliness of self-reporting, any additional cooperation by the disclosing party, the litigation risk involved with the violation, and the finances of the disclosing party.

The vehicle that providers and suppliers should use to seek relief is the Self-Referral Disclosure Protocol (SRDP), released Sept. 23 by the Centers for Medicare and Medicaid Services (CMS), as required by this year's Patient Protection and Affordable Care Act (Public Law No. 111-148).

The ban on physician self-referrals, known as the Stark law, prohibits a physician from making Medicare or Medicaid referrals for certain

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New Money to Help Support Lab Technology, Personnel Hiring and Training

Nearly $100 million in grants have been awarded to support public health programs in states and local communities, including health information technology and personnel hiring and training at public health laboratories.

The grants were announced Sept. 24 by Health and Human Services Secretary Kathleen Sebelius. The money comes primarily from the Prevention and Public Health Fund authorized under the health care reform law enacted this year.

More than $75 million worth of the grants will go to fund key state and local public health programs supported through the Centers for Disease Control and Prevention (CDC).

Another $26.2 million in grants will go to state and community substance abuse and mental health programs from the Substance Abuse and Mental Health Services Administration (SAMHSA).

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Medicare Creates New Way, *from p. 1*

designated health services to an entity with which he or she (or an immediate family member) has a financial relationship (ownership, investment, or compensation), unless an exception applies.

Designated Health Services Under Stark Self-Referral Law

- ❑ Clinical laboratory services
- ❑ Physical therapy services
- ❑ Occupational therapy services
- ❑ Outpatient speech-language pathology services
- ❑ Radiology and certain other imaging services
- ❑ Radiation therapy services and supplies
- ❑ Durable medical equipment and supplies
- ❑ Parenteral and enteral nutrients, equipment, and supplies
- ❑ Prosthetics, orthotics, and prosthetic devices and supplies
- ❑ Home health services
- ❑ Outpatient prescription drugs
- ❑ Inpatient and outpatient hospital services

In addition to banning self-referrals of the above services, the Stark law bars presenting or causing to be presented claims to Medicare (or billing another individual, entity, or third-party payer) for those referred services.

It also establishes a number of specific exceptions and grants CMS the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse.

Open to All

The SRDP is open to all health care providers of services and suppliers, whether individuals or entities, and is not limited to any particular industry, medical specialty, or type of service.

The fact that a disclosing party is already subject to government inquiry (including investigations, audits, or routine oversight activities) will not automatically preclude a disclosure. The disclosure, however, must be made in good faith, with full cooperation.

A Key Difference to Note

The protocol cannot be used to obtain a CMS determination as to whether an actual or potential violation of the Stark law occurred. It is separate from the CMS advisory opinion process on physician self-referrals.

The SRDP is designed, CMS said, "to facilitate the resolution of only matters, that in the disclosing party's reasonable assessment, are actual or potential violations of the law. Thus, the disclosing party should make a submission with the intention of resolving its overpayment liability exposure for the conduct it identified. As provided in the statute, no payment can be made for designated health services furnished in violation of the law."

What Must Be Disclosed to CMS?

All disclosures must be submitted electronically, and an original and one copy mailed to CMS. The self-referral disclosure must include:

- ❑ Name, address, national provider identifier (NPI), CMS certification number, and tax identification number of the disclosing party.
- ❑ Description of the potential self-referral violation being disclosed.
- ❑ Why the disclosing party believes a violation has occurred (this should include a legal analysis).
- ❑ How the potential violation was discovered.
- ❑ Whether the disclosing party has had any past history of violations or criminal actions.
- ❑ Description of any compliance programs in place at the time of the potential violation.
- ❑ Any notices sent to other government agencies regarding the potential violation.

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focus on: *Medicare Payment Policy*

Preliminary Pay Rates for New Medicare Lab Codes

The Centers for Medicare and Medicaid Services (CMS) has posted preliminary payment determinations for new test codes on the 2011 Medicare Part B clinical laboratory fee schedule. The posting follows the public comment period on the codes that ran from July through mid-September (NIR *10, 15/Aug., pp. 1, 2-3*).

CMS will consider comments received and publish its final decisions in the 2011 Part B lab fee schedule, expected to be released in November.

As it typically does, CMS opted for the crosswalk method to price most but not all the codes (*see table, pp. 4-5*). Under this method, a new test code is matched to a similar code on the fee schedule and paid at the lower of the local fee schedule amount or the national fee cap. Most lab codes are paid at the cap.

For new Current Procedural Terminology (CPT) drug screening code 801XX, CMS made no recommendation. Instead, the agency created a new set of HCPCS G codes for drug screening, depending on the complexity of the test method assigned under the Clinical Laboratory Improvement Amendments (CLIA)—waived, moderate, or high.

Drug Screening Code Reshuffle

While acknowledging that the CPT committee created 801XX to replace G0430, Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure, CMS said it has discovered that neither of these codes is properly described in order to control improper payment, billing, and utilization. The agency will delete G0430, edit the descriptor for G0431 to designate use of a CLIA high-complexity test method, and create a new code GXXX1 to indicate use of a waived or moderate-complexity test method.

Reconsideration Requests

CMS also accepted requests to reconsider the pricing of five codes currently on the lab fee schedule. It agreed to crosswalk four and delete one, G0430, as part of the above noted switch to a new set of drug screening codes, based on CLIA complexity. Preliminary crosswalks for the CPT codes under reconsideration are:

- ❏ 84145, Procalcitonin (PCT). To 82308, Calcitonin, currently capped at $38.36
- ❏ 84431, Thromboxane metabolites, including thromboxane if performed, urine. To 84443, Thyroid stimulating hormone (TSH), now capped at $24.06
- ❏ 86352, Cellular function assay involving stimulation (e.g., mitogen or antigen) and detection of biomarker (e.g., ATP). To 86353 x 2, Lymphocyte transformation, mitogen (phytomitogen) or antigen induced blastogenesis PLUS 82397 x 2, Chemiluminescent assay, or a total of $180.92
- ❏ G0431, Drug screen, qualitative; multiple drug classes by high-complexity test method (e.g., immunoassay, enzyme assay), each specimen. To G0430 x 5, or a total of $104.15

Next Step

The preliminary payment determinations and the CMS rationale for each are found at *www.cms.gov/ClinicalLabFeeSched/*. Click under Laboratory Public Meetings.

Medicare Pricing for New 2011 Lab Fee Schedule Codes:
CMS Announces Preliminary Payment Decisions

Code/Descriptor	*Preliminary Crosswalk Decision*	*Current National Fee Cap**
DRUG TESTING		
801XX, Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure	No recommendation	N/A
CHEMISTRY		
829XX, Gastric acid analysis, includes pH if performed, each specimen	82926, Gastric acid, free and total, each specimen	$7.81
838XX, Microfluidic analysis utilizing an integrated collection and analysis device, tear osmolarity	83909, Molecular diagnostics; separation and identification by high-resolution technique (e.g., capillary electrophoresis), each nucleic acid preparation	$24.01
841XX, Placental alpha microglobulin-1 (PAMG-1), cervicovaginal secretion, qualitative	82731, Fetal fibronectin, cervicovaginal secretions, semiquantitative	$92.26
IMMUNOLOGY		
864XX, Tuberculosis test, cell mediated immunity antigen response measurement; enumeration of gamma interferon-producing T-cells in cell suspension	86480, Tuberculosis test, cell mediated immunity measurement of gamma interferon antigen resp	$88.77
MICROBIOLOGY		
875XX1, Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, reverse transcription and amplified probe technique, each type or subtype	87521, Infectious agent detection by nucleic acid (DNA or RNA); hepatitis C, amplified probe technique PLUS 83902, Molecular diagnostics; reverse transcription	$70.60
875XX2, Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or subtypes, reverse transcription and amplified probe technique, first two types or subtypes	87801, Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; amplified probe(s) technique PLUS 83902, Molecular diagnostics; reverse transcription	$120.80
875XX3, Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or subtypes, multiplex reverse transcription and amplified probe technique, each additional influenza virus type or subtype beyond two (List separately in addition to code for primary procedure)	83901, Molecular diagnostics; amplification, target, multiplex, each additional nucleic acid sequence beyond two (List separately in addition to code for primary procedure) PLUS 83896, Molecular diagnostics; nucleic acid probe, each	$29.75
879XX, Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, other region (e.g., integrase, fusion)	87901, Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease, at half the payment rate	$184.36

Medicare Pricing for New 2011 Lab Fee Schedule Codes:
CMS Announces Preliminary Payment Decisions

Code/Descriptor	*Preliminary Crosswalk Decision*	*Current National Fee Cap**
HEMATOLOGY AND COAGULATION		
855XX, Phospholipid neutralization; hexagonal phospholipid	85597, Platelet neutralization	$25.75
TRANSFUSION MEDICINE		
869XX, Blood typing; antigen testing of donor blood using reagent serum, each antigen test	86905, Blood typing; RBC antigens, other than ABO or Rh(D), each	$5.48
HCPCS CODES		
G0432, Infectious agent antibody detection by enzyme immunoassay (EIA) technique, HIV-1 and/or HIV-2, screening. Short descriptor: EIA HIV-1/HIV-2 screen	86703, Antibody, HIV-1 and HIV-2, single assay	$19.65
G0433, Infectious agent antibody detection by enzyme-linked immunosorbent assay (ELISA) technique, HIV-1 and/or HIV-2, screening. Short descriptor: ELISA HIV-1/HIV-2 screen	86703, Antibody, HIV-1 and HIV-2, single assay	$19.65
G0435, Infectious agent antibody detection by rapid antibody test, HIV-1 and/or HIV-2, screening. Short descriptor: Oral HIV-1/HIV-2 screen	87804, Infectious agent antigen detection by immunoassay with direct optical observation; Influenza	$17.18
GXXX1, Drug screen, other than chromatographic; any number of drug classes, by CLIA-waived test or moderate complexity test, per patient encounter	G0430, Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure	$20.83
G9143, Pharmacogenomic testing for Warfarin response	83891, Molecular diagnostics; isolation or extraction of highly purified nucleic acid, each nucleic acid type (i.e., DNA or RNA) PLUS 3 x 83896, Molecular diagnostics; nucleic acid probe, each PLUS 83900, Molecular diagnostics; amplification, target, multiplex, first two nucleic acid sequences PLUS 83901, Molecular diagnostics; amplification, target, multiplex, each additional nucleic acid sequence beyond two (List separately in addition to code for primary procedure) PLUS 3 x 83908, Molecular diagnostics; amplification, signal, each nucleic acid sequence PLUS 83912, Molecular diagnostics; interpretation and report	$172.76

CPT codes © American Medical Association Digits to be finalized in *CPT 2011*.
*National fee caps are scheduled to be reduced 1.75 percent as of Jan. 1, 2011.

Medicare Creates New Way, *from p. 2*

- ❏ Whether the disclosing party is aware of the matter being under investigation by any other government agency.

The disclosing party also must submit a full financial analysis of any money that is potentially owed as a result of Stark law violations.

After receiving an SRDP, CMS may ask for additional documents to verify the disclosure and assist the inquiry. Disclosing parties will have at least 30 days to respond to any requests.

CMS will review the circumstances of the matter disclosed to determine an appropriate resolution. In some instances, Medicare contractors may be responsible for processing any identified overpayment.

Some Caveats to Note

CMS is not bound by any conclusions made by the disclosing party and is not obligated to resolve the matter in any particular way. Nevertheless, the agency says it will work closely with anyone who structures the disclosure in accord with the SRDP to reach an effective and appropriate solution.

As a condition of disclosing a matter, the disclosing party agrees that no appeal rights attach to claims relating to the conduct disclosed if resolved through a settlement agreement. If the disclosing party withdraws or is removed from the protocol, it may appeal any overpayment demand in accord with applicable regulations.

Federal Advisory Panel on Genetics Disbands

The federal charter authorizing the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) is not being renewed because the group had fulfilled its mandate, the panel announced in a note to the public. The final meeting, held Oct. 5-6, concentrated on completing an education and training report and on drawing concluding thoughts about other pending issues, such as genomic data sharing, comparative effectiveness research and clinical utility, and the implications of affordable whole-genome sequencing.

In its nearly 10 years of operation, the statement noted, SACGHS has addressed all the major topics delineated in its charter, issuing comprehensive reports and providing advice and recommendation on a broad range of topics. They included integration of genetic and genomic technologies into health care and public health; the clinical, public health, ethical, economic, legal, and societal implications of these technologies; gaps in research and data collection; the impact of patent policy and licensing practices; and how genetic and genomic technologies are used in other settings such as education, employment, insurance, and law.

SACGHS has been no stranger to controversy, weighing in this year on the gene patenting issue and its implications for personalized medicine, with a majority calling for legislation to exempt from liability for gene patent infringement "anyone making, using, ordering, offering for sale, or selling a test developed under the patent for patient care purposes" and those who use patent-protected genes in research. SACGHS also urged the Food and Drug Administration to expand its oversight of genetic testing (which the agency is now planning to do). The panel also was the first to call for a genetic test registry, which the National Institutes of Health will establish in 2011.

California Tells Labs to Audit Charges to Medicaid Program

The California Department of Health Care Services is requiring that all laboratory providers serving beneficiaries in the state's Medicaid program, Medi-Cal, conduct a self-audit and report what they charge the program compared to rates charged to other payers, private pay patients, and clients.

The self-audit is the result of the department's Laboratory Price Sweeps Special Project, which found that lab providers have routinely charged and been reimbursed by Medi-Cal with rates higher than the rates they charge to other payers for the same services under comparable circumstances.

In a Sept. 20 letter, Jan Inglish, N.P., chief of the medical review branch of the audits and investigations unit, said the aim is to ensure compliance with the state's requirement that "no provider shall charge for any service or any article more than would have been charged for the same service or article to other purchasers of comparable services or articles under comparable circumstances."

The audit covers procedures for the period from July 1, 2009, through Dec. 31, 2009. "Participation is mandatory. Failure to cooperate may lead to sanctions up to and including suspension from Medi-Cal," the letter warned.

Labs are to follow these steps:

❏Review all third-party payers and/or private pay patients/clients' fee schedules and identify any rates that are lower than the Medi-Cal published rates. The latter are at *http://files.medi-cal.ca.gov/pubsdoco/rates/rateshome.asp.*

❏ In an Excel spreadsheet, list by procedure code and payer type the lower rates identified and the corresponding Medi-Cal published rate.

❏ Mail the spreadsheet and supporting fee schedules no later than Oct. 20, 2010, to the medical review branch of the audits and investigations unit.

An example of the self-reporting spreadsheet was provided in the letter, as follows:

	PROCEDURE CODES	PROCEDURE CODES DESCRIPTION	PAYER TYPE (NAME)	RATE CHARGED FOR PRIVATE PAY/CLIENT	MEDI-CAL REIMBURSEMENT RATE	RATE DIFFERENCE
Example 1	CPT code	Test name	Clinic name	$35.00	$38.41	$3.41
Example 2	CPT code	Test name	Physician name	$4.25	$8.50	$4.25

Separately, the California attorney general is pursuing a whistleblower lawsuit it joined last year against a group of seven labs for alleged illegal kickbacks under Medi-Cal. Two have settled and one is in settlement discussions, while trial dates have been set for four others, including national giants Quest Diagnostics and Laboratory Corporation of America (NIR, *10, 17/Sept. 23, p. 1*). All the defendants have denied any wrongdoing. The suit, filed by Chris Riedel, the CEO of Hunter Laboratories in Campbell, Calif., alleges that the labs charged Medi-Cal up to six times more for tests compared to what they charged other clients for the same tests over the past 15 years, in violation of Medi-Cal's "lowest rate" requirement. In addition, the AG's office is pursuing a case against Primex Clinical Laboratories Inc., which was not included in the whistleblower complaint, said AG spokesperson Rebecca MacLaren.

New Money, *from p. 1*

For a breakout of grants by state, go to cdc.gov and click on Press Room.

Of the money that goes to CDC, approximately $26.4 million will be used to increase epidemiology, laboratory, and health information systems capacity at health departments in all 50 states, two territories, and the six largest local jurisdictions.

The awards will support:

- ❑ Hiring and training of epidemiologists, laboratory scientists, and health information specialists who can work on multiple infectious diseases;
- ❑ Increasing the number of modern, well-equipped public health labs using electronic laboratory information systems to manage and exchange information effectively between labs and public health departments; and
- ❑ Developing capacity for public health departments to participate in meaningful use of electronic health records through implementation of electronic laboratory-based reporting according to national standards.

CDC awarded approximately $6.8 million to eight national nonprofit professional public health organizations to support efforts by state, tribal, local, and territorial health departments "to ensure successful adoption of effective practices that strengthen core public health infrastructure investments."

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