G-2 Compliance Report

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For Hospitals, Laboratories and Physician Practices

N.Y. Prohibits Labs From Donating EHRs To Referring Physicians

The New York Department of Health is prohibiting laboratories operating in the state from providing electronic health record (EHR) systems and software packages to referring physicians even though federal law allows labs to donate or cost-share up to 85 percent of the cost of EHR software, technology, and training.

In a Sept. 27 letter sent to clinical laboratories operating in New York state (NYS), the Department of Health said that state rules "do not allow cost sharing; therefore, provision of EHR, software, and training that otherwise may be permitted under federal law is prohibited in connection with a laboratory's operating in NYS." The letter noted that the preamble to the federal EHR regulations, published in the *Federal Register* Aug. 8, 2006, makes it clear that the EHR-related federal payment allowance does not preempt state laws and regulations.

The policy stated in the letter presumably would apply to patholo-

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Federal Compliance Blitz: Enforcement Challenges Ahead for Labs and Pathologists

Given the federal government's recent efforts to step up its fraud enforcement, now is a good time for all health care providers, including clinical laboratories and pathologists, to review policies and procedures to ensure they are in compliance with all applicable laws and regulations, advises Hope Foster, an attorney with Mintz Levin in Washington, D.C.

Foster addressed the challenges ahead during Washington G-2 Reports' 28th Annual Lab Institute, held in Arlington, Va., Oct. 13-15.

In the past 18 months, lawmakers have passed a number of laws giving the feds increased enforcement authority, including the Fraud Enforcement and Recovery Act of 2009 (FERA) and the Patient Protection and Affordable Care Act (PPACA). In May 2009 the departments of Justice and Health and Human Services announced a new interagency initiative to combat Medicare fraud—the Health Care Fraud Prevention and Enforcement Action Team (HEAT).

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Federal Compliance Blitz, *from page 1*

In fall 2009, President Obama announced a new interagency financial fraud enforcement task force and proposed a budget of $1.7 billion for the Health Care Fraud and Abuse Control Program (HCFACP). And in March 2010, the president issued a memorandum regarding finding and recapturing improper payments, which effectively expanded the use of payment recapture audits.

"Follow the money," notes Foster. "If you want to see what the government cares about, see where it's spending its money. And if it's spending more money on enforcement, it means there will be more enforcement."

These new initiatives, taken together with laws and regulations already in place, amount to one of the toughest health care fraud enforcement climates in a number of years, says Foster. Among key changes:

The anti-kickback intent standard has been revised. Under the new standard, a person need not have actual knowledge of the law or specific intent to commit a violation. Essentially this lowers the level of intent required to provide a violation.

"Follow the money. If you want to see what the government cares about, see where it's spending its money. And if it's spending more money on enforcement, it means there will be more enforcement."
– Hope Foster

PPACA adds language linking anti-kickback violations to the False Claims Act. PPACA also makes changes to the FCA, which under certain circumstances, bars qui tam cases based on "publicly disclosed" allegations unless the individual bringing the suit was the "original source" of the information. Under PPACA, the government can oppose dismissal of such a qui tam case. In addition, the law further defines "public" as being at the federal level.

PPACA changes the threshold for qualifying as an original source under the FCA, modifies the requirements that the relator has "direct and independent knowledge," and mandates that for prefiling disclosures, the relator must have knowledge of the information that is "independent of" and that "materially adds to" the previously disclosed information about the allegations or transaction.

CMS has tried to address some of the problems related to the Stark prohibition on self-referrals, including highly detailed rules, strict liability, mandatory compliance with exceptions, link to FCA, and potentially ruinous penalties for de minimis violations. In March 2009, the HHS Office of Inspector General announced that there would be no Stark law self-disclosure under its self-disclosure protocol unless there was a "colorable anti-kickback violation." As a result, CMS on Sept. 23 published its own voluntary self-disclosure protocol to address violations of the Stark law (*see related article on p. 4*).

PPACA provides a new exception under the Stark law for "[R]emuneration which promotes access to care and poses a low risk of harm to patients and federal health care programs." This applies to items and services related to the medical care of the patient, when there is a good-faith determination that the patient is in financial need.

PPACA requires that Medicare and Medicaid overpayments must be reported, explained, and returned to the appropriate entity within 60 days after identification or on the date any corresponding cost report is due, whichever is later.

PPACA expands the types of conduct subject to CMPs to include failing to provide the OIG timely access for audits, investigations, or certain other statutory functions; knowingly making, using, or causing to be made or used a false

record or statement material to a false claim for payment for items or services; knowingly making a false statement, omission, or misrepresentation on an enrollment application, bid, or contract; and ordering or prescribing items or services (including lab tests) during any period when the person ordering or prescribing has been excluded.

PPACA also requires establishment of a compliance program as a condition of enrollment under the Medicare and other federal health programs, eliminates limitations on prepayment review, and expands the Recovery Audit Contractor program to cover Medicaid and Medicare Parts C and D.

Laboratory Compliance Issues

All of the enforcement changes made in the past year and a half have the potential to affect laboratories and pathologists, notes Foster. In fact, laboratory-related compliance issues reach all aspects of laboratory operations, including sales and marketing, relationships with referrers and those who arrange for and recommend referrals, test ordering, test performance, test reporting, and billing.

Labs should carefully consider relationships with referral sources, says Foster, noting that this is a fertile area for enforcement. "I spend a lot of time looking at relationships because there has been a significant uptick in enforcement in this area," she says, adding that both the AKS and the Stark law are implicated. Recent laws have expanded the definition of "inducement," the definition of "remuneration," and enforcement of "arranging for" or "recommending" prohibitions.

In terms of test ordering, labs must consider the identity of the test orderer, clarity of the test order, need for individualized test orders, provision of complete information (including diagnosis information), procedures for obtaining missing information, provision for memorializing the receipt of missing information, add-on requests, and retention of information.

> ***" I spend a lot of time looking at relationships because there has been a significant uptick in enforcement in this area."***
> ***– Hope Foster***

Test performance issues include compliance with CLIA or other applicable performance standards, compliance with manufacturer's label or with CLIA validation requirements if procedure is modified, compliance with CLIA validation requirements for laboratory-developed tests, compliance with requirements applicable to proficiency testing, and licensure of test-performing personnel.

Questions that labs must answer when determining compliance with test reporting requirements include: To whom is the report sent? Can reports be sent to patients? How do you respond to requests for copies of reports? What does the report say? Can the verbiage be construed to be the unauthorized practice of medicine? Have all tests for which results are reported been ordered?

Potential trouble spots in billing include identification of the proper party to bill, billing an inappropriate party, billing for tests not performed, billing for tests not ordered or improperly ordered, and use of improper CPT codes. In addition, labs must avoid diagnosis code steering or jamming, billing for services ordered pursuant to an inappropriate or unlawful referral, knowingly billing for uncovered services, and billing for medically unnecessary services and tests of inadequate quality.

"These are real issues that labs have problems with," stresses Foster. "I have defended labs in all of these areas. They are not to be taken lightly."

Stark SDRP Protocol Offers Reduced Repayment Potential

The Centers for Medicare and Medicaid Services' newly released Stark self-referral disclosure protocol (SRDP) will allow providers the possibility of a reduced repayment resulting from any Stark law violations, Troy Barsky, director of CMS's Division of Technical Payment Policy said Sept. 27 at the 2010 Fraud and Compliance Forum in Baltimore.

Barsky said that the accuracy of a provider's disclosure, as well as the speed in filing it, would help determine whether a repayment would be reduced.

"The speed of verification of a disclosure will largely depend on the quality of the information received," Barsky said at the forum, sponsored by the American Health Lawyers Association and the Health Care Compliance Association.

The SRDP, which was released Sept. 23, allows a provider to self-report a probable violation of the Stark law, which prohibits referrals of Medicare and Medicaid patients to entities with which physicians or their immediate family members have a financial relationship if the referral is for the furnishing of designated health services.

Barsky also said that the SRDP will suspend the normal 60-day deadline for returning overpayments. "The clock is stopped when CMS receives the protocol electronically," he said. The repayment suspension will continue as long as a provider's protocol is being reviewed by CMS, Barsky said.

Advisory Opinions

The SRDP should not be used by providers looking for an advisory opinion, Barsky said, and it should specifically relate to Stark issues. "We assume that any issues we receive in protocols will not be applicable to the Department of Health and Human Services Office of Inspector General or the Department of Justice," he said.

Katherine A. Lauer, an attorney with Latham & Watkins, San Diego, also said that providers should avoid using the protocol for advisory opinion purposes and said that the SRDP should be used

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Yost Receives Laboratory Public Service Award

Judy Yost

Judy Yost, M.T.(ASCP), the top official responsible for the Clinical Laboratory Improvement Amendments (CLIA) program at the Centers for Medicare and Medicaid Services (CMS), received the 2010 Laboratory Public Service National Leadership Award at this year's 28th Annual Lab Institute, held by Washington G-2 Reports in Arlington, Va., Oct. 13-15.

The award, sponsored by Kellison & Co., recognizes singular accomplishments that directly enhance patient care and the laboratory profession in one or more specific areas: basic and applied research, business creativity and innovations, public policy, and lifetime achievement.

In presenting her with this 17th annual award, Dennis Weissman, founder and former head of Washington G-2 Reports, noted, "Judy has been a staunch defender of quality in the clinical laboratory during her many years of dedicated service at the national level. As head of the CMS office for CLIA virtually since its inception, she is responsible for the oversight and administration of the regulatory program in a manner that promotes testing quality and accuracy.

"But on a more fundamental level, as expressed in one of our recipient's nominating letters, she has 'been a tireless educator and communicator related to the application of CLIA regulations in the laboratory and never hesitates to make herself available to the public, an organization, or an individual for the purposes of promoting quality laboratory testing and helping people make sense of the complex and sometimes difficult regulations that govern laboratories.'"

Yost is currently director of the Division of Laboratory Services at CMS. Prior to joining CMS, she was the administrative director of progressively larger clinical laboratories and other clinical services in health systems.

COMPLIANCE
PERSPECTIVES

Peter Kazon, Esq.

Gaining a Measure of Control: Advanced Compliance Strategies for Labs

With the federal government stepping up its crackdown on health care fraud and abuse, even the smallest mistake or oversight can land a lab in hot water, warns Peter Kazon, an attorney with Alston & Bird in Washington, D.C. Kazon addressed key compliance concerns for labs at Washington G-2 Reports' 28th annual Lab Institute, held in Arlington, Va., Oct. 13-15.

"We're entering a period now where we're going back to the terrible '90s , where there's going to be a lot of attention paid to the nuts and bolts of test ordering and billing," says Kazon. "Vicki Robinson, chief of industry guidance at the [Department of Health and Human Services Office of Inspector General] recently gave a speech in which she said she expected increasing attention to be paid to lab services and stated that now is a good time for labs to look at their compliance plans."

While the government estimates that it loses about $700 million a year in health care fraud and abuse, much of that actually comes from documentation errors or other problems with ordering, billing, and coding. The health care reform legislation passed earlier this year expands the government's authority in conducting audits and reviews. There are a lot of entities now looking over your shoulder, says Kazon, from Zone Program Integrity Contractors (ZPICs) to Recovery Audit Contractors (RACs) to Medicare Comprehensive Error Rate Testing (CERT) program contractors.

Some of these auditors actually have financial incentive to find errors, and all are essentially looking for mistakes. Unfortunately, they frequently don't know or understand the rules, which means that labs have to be prepared to counter incorrect conclusions. Auditors will look at everything, warns Kazon, from documentation errors to potential overutilization. "They are almost always looking for easy errors," he says. Was the test ordered? Was it medically necessary? Is it documented in the medical record? Below we examine these potential trouble spots in more detail.

Was the Test Ordered and Documented?

While this seems like a basic question, there actually is an incredible amount of confusion around this issue, explains Kazon, and the Centers for Medicare and Medicaid Services (CMS) has recently added to this confusion in its proposed changes to the Medicare physician fee schedule for 2011, released in July.

The confusion typically revolves around whether there is a physician signature or not. While the laboratory-negotiated rulemaking established the policy that no physician signature is necessary on a lab requisition as long as the physician has documented the ordering of a specific service in the medical record, CMS has now proposed requiring the signature of a physician or nonphysician practitioner on all lab requisitions and orders. The proposal has drawn opposition from groups

representing clinical laboratories. CMS is expected to address comments in the final physician fee schedule rule that will be published in the next couple of weeks.

Under current policy, if there is no signature on the lab requisition, then there has to be evidence in the medical record that the physician intended to order the test. Recently, CMS further explained in the Medicare Program Integrity Manual that the medical record must be "authenticated by the author via a handwritten or electronic signature."

According to the manual, the physician's signature must be legible. Where it is not legible, CMS has established a complete list of rules for when it can be considered authentic. Alternative ways of documenting the signature include external evidence, a signature log, and physician attestation (*see box*). A signature log is documentation that lists the typed or printed name of the author associated with a signature or initials. A signature attestation statement must be signed and dated by the author of the medical record entry.

Attestation Statement

According to CMS, the following language is acceptable for an attestation statement, though not mandatory:

"I, _____ [print full name of the physician/practitioner], hereby attest that the medical record entry for ____ [date of service] accurately reflects signatures/notations that I made in my capacity as _____ [insert provider credentials, e.g., M.D.] when I treated/diagnosed the above listed Medicare beneficiary. I do hereby attest that this information is true, accurate, and complete to the best of my knowledge and I understand that any falsification, omission, or concealment of material fact may subject me to administrative, civil, or criminal liability."

Was the Test Medically Necessary?

This is another potential trouble spot for labs because medical necessity is determined by the referring physician, not the laboratory. Auditors will look to make sure the appropriate ICD-9 diagnostic information is included and is consistent with the documentation in the patient's chart. The ICD-9 diagnostic information must be clinically relevant for the test ordered and coded to the highest degree of specificity. When there is not appropriate ICD-9 diagnostic information (narrative or numeric) provided to support the medical necessity of the test, or if there are frequency limitations to the tests, the lab will need to obtain a signed advanced beneficiary notice (ABN) from the patient.

However, even when a laboratory receives acceptable ICD-9 codes from the physician, an auditor will frequently look for additional evidence of medical necessity in the record, adds Kazon.

Protecting Your Lab

The best line of defense against errors or mistakes is to have an effective compliance plan in place and to review internal processes. In the past, laboratory compliance plans were voluntary, but under the new health reform law the plans will be mandatory.

In reviewing your internal processes, you should look at the following:

- Requisitions. Do they clearly require a physician to order the test being performed? Is reflex testing clearly ordered? Are standing orders regularly updated and clearly documented? Is there a statement regarding medical necessity? Do you want to request a physician's signature?
- Are the rules for accessioning clear?
- How are incomplete or unclear orders handled?
- Is follow-up with physicians documented?
- Do you send annual "Dear Doctor" letters reminding physicians of issues related to documentation?

- If you have electronic orders, are there safeguards in place and are they documented?

What If You Get Audited?

Given the increased federal focus on eliminating fraud and recovering overpayments, chances are good that your lab will be audited at some point. Kazon recommends you ensure that your employees know what to do if a letter from an auditor arrives. The letter should be taken seriously and staff should respond within the allotted time frame, he advises.

"Be proactive," says Kazon. "The auditor is not there to help you. They are basically there to find mistakes. Don't rely on them to get the information you need. You need to get the information yourself."

Kazon advises gathering all the information you have in your files, including claims, orders, and results. If you have an electronic ordering system that was used, document the security features showing the physician alone had access and the ability to order lab testing. Work with physicians to obtain information from their files, he says. For example, see if they will let you copy information in their medical records, and if they have an electronic health record, ask if they will let you make copies of "screenshots."

Keep copies of whatever is submitted to the auditors and document any conversations you have with them, says Kazon. As the matter moves along, request copies of any information they have received from physicians or other sources. If necessary, consider an expert who can help explain the need for testing.

Kazon emphasizes that you do have the right to appeal any findings. Make the case to your Medicare administrative contractor (MAC) if they seek repayment. If an auditor has extrapolated claims or numbers, consider hiring a statistical expert who can review what was done. "Remember, it's easier to do all this earlier in the process than later," says Kazon.

Stark Protocol, *from page 4*

only when there is a high probability of a Stark law violation.

"If you're not sure you've got a problem, you shouldn't get into the protocol. You should assume once you're in the protocol, there will be some repayment happening," she said, addressing a session of the forum.

The SRDP is available at www.cms.gov/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf.

Lauer also said that providers should be happy about the provision that potentially allows providers to repay the government for less than the full amount of the original overpayment.

In addition to filing an SRDP with CMS, Lauer said that providers have several other options when it comes to disclosing a Stark law violation, including disclosing to Medicare Administrative Contractors (MAC), the OIG, and the local U.S. attorney's office.

Any submissions to a MAC will require a full refund of the overpayments, while the OIG will only accept a submission if the potential violation also implicates the anti-kickback statute, Lauer said. As for disclosing a Stark law violation to a U.S. attorney's office, Lauer said that each office handles cases differently but that providers should expect to pay multiples of their overpayment amount.

N.Y. Prohibits Labs From Donating EHRs, *from page 1*

gists as well, says Jane Pine Wood, an attorney with McDonald Hopkins (Dennis, Mass.), who advises pathology groups.

The rapid and widespread adoption of EHRs by both hospitals and physician practices is unprecedented and creates several challenges for labs, including being asked by health care providers to pay for or contribute to the cost of the interface to client EHRs or being asked to donate or cost-share up to 85 percent of the cost of new EHR software, notes the letter.

"I would advise my clients to take a wait-and-see approach for right now until we have more answers."
– Jane Pine Wood

While the federal and state governments are involved in a variety of efforts to encourage the use of health information technology, the Department of Health has become aware of abusive business practices, says the letter—"specifically, that clinical laboratories are offering new EHRs and software packages as an inducement for practitioners to refer patient specimens for testing, resulting in a financial benefit conferred to the practitioner."

While labs operating in NYS may not donate EHRs to physicians, they may provide limited types of software and hardware that facilitate test ordering and transfer and storage of laboratory-generated data, says the Department of Health. For example, labs may:

1 Interface their laboratory information system to the client's existing EHR to enable seamless laboratory test ordering and laboratory test reporting and facilitate other laboratory-related functions (see item 2) and may assume, as a cost of doing business, the cost of a such a limited interface;

2 Provide to a practitioner computer hardware, software, and information technology training and supplies that are restricted to laboratory-related functions that enable the practitioner to a) order tests from the laboratory, including access to a directory of services (i.e., specimen type, collection container, and test information); b) receive, access, print, and store test results received from the laboratory, including storing cumulative results for individual patients; c) transmit data necessary for the laboratory to prepare requisitions and generate bills, invoices, or claims for reimbursement; and d) transfer laboratory data received from the lab to any computer system maintained by the practitioner;

3 Provide computer hardware and software as noted above that also contains functionality that permits a practitioner to make referrals to other laboratories and/or provides access to other laboratories' Internet portals;

4 Provide to a Regional Health Information Organization (RHIO) or health information exchange (HIE) computer equipment and supplies, information technology, and software in accordance with the requirement in item 2 above. Laboratories may not contribute to the RHIO's or HIE's acquisition costs for EHR components, including software interfaces, or a practitioner's costs of participation unless in accordance with the requirements in item 2 above. Nothing in this bullet requires a laboratory to provide such EHR components to a RHIO or HIE for its participants.

The Department of Health also says the labs operating in New York state must retrieve all computer equipment placed with the health services provider and related unused supplies and discontinue paying for an interface upon termination of a laboratory services agreement or arrange for a one-time purchase at fair-market value that transfers ownership of hardware and software to the practitioner.

Potential Problems for Labs, Pathologists

Several health care attorneys contacted by G-2 Reports say the letter could create significant problems for labs and pathologists who thought they were covered by the federal exception that allows labs to pay up to 85 percent of the cost of EHR technology, software, and training. Enforcement of this policy could require labs and pathologists to undo current contracts with referral sources and possibly even seek reimbursement for the share of the cost they have paid for.

Rob Mazer, an attorney with Ober Kaler (Baltimore) notes that physicians may try to enforce any contracts they have with labs covering EHR software, technology, and training, particularly since the physicians likely have signed a contract with the EHR vendor. Mazer says he hopes the New York Department of Health will provide a reasonable amount of time for labs to unwind existing contracts.

While this is not necessarily a new policy, Wood, from McDonald Hopkins, notes that the policy has never been widely publicized or enforced and many labs and pathologists may have been unaware of the state prohibition. It is unclear from the letter just how the policy will be enforced. Attempts to reach Betty Kusel, director of regulatory affairs and deputy director of the Division of Laboratory Quality Certification for the New York Department of Health, were unsuccessful. A staffer in the department told G-2 that Kusel retired Sept. 28, the day after the letter was sent.

For now, Wood advises that labs wait for further clarification from the department before starting the process of undoing agreements. "I would advise my clients to take a wait-and-see approach for right now until we have more answers," she says.

CMS Proposed Rule Would Add Background Checks, Fingerprinting to Provider Screening

A proposed rule from the Centers for Medicare and Medicaid Services (CMS) would create enhanced screening procedures, such as fingerprinting and criminal background checks, for high-risk providers and suppliers enrolling and participating in federal health care programs.

The proposed rule, published in the Sept. 23 *Federal Register*, would implement provisions in the Patient Protection and Affordable Care Act (PPACA) pertaining to entering and revalidating status in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). Comments on the rule are due by Nov. 16.

The proposed rule, published on Sept. 23, 2010, is available at www.federalregister.gov.

Donald Berwick, CMS administrator, said the enhanced screening provisions were part of an overall effort to switch from a pay-and-chase enforcement model to an enforcement model based on preventing the possible payment of fraudulent claims. He said CMS will take advantage of various advanced technology and data analysis tools to pursue the proposed screening measures.

The PPACA-based screening provisions provide the secretary of health and human services with new discretionary authority to tighten the level of screening for providers and suppliers operating within Medicare, Medicaid, and CHIP. Fingerprint checks, for example, have never been used in the screening process, and criminal background checks have been used sparingly.

The proposed rule said that fingerprint checks will allow CMS to verify an individual's identity, determine whether that person is eligible for enrollment, and prevent any identity theft. Such a system would protect Medicare, Medicaid, and

CHIP from fraudulent schemes, the proposed rule said. Criminal background checks also would help prevent fraud from happening in the first place by weeding out criminals attempting to enroll in the programs.

Tiered Levels of Risk

Under the proposed rule, all providers and suppliers would be placed in one of three risk levels (limited, moderate, and high), based on an assessment of their overall risk of fraud, waste, and abuse. Screening procedures would differ for every risk level, with high-risk providers and suppliers receiving the most attention.

For example, a limited-risk provider/supplier would have to verify any provider/supplier requirements set forth by Medicare, verify his or her licensing, and undergo database checks before and after enrollment that would verify Social Security numbers, tax delinquency, and any exclusions from the Department of Health and Human Services Office of Inspector General.

A moderate-risk provider/supplier would face the additional provision of unscheduled site visits, while a high-risk provider/supplier would face all provisions, as well as criminal background checks and fingerprinting checks. The new procedures would be applicable for newly enrolling providers/suppliers on March 23, 2011, as well as for all currently enrolled Medicare, Medicaid, and CHIP providers/suppliers.

CMS did acknowledge that independent clinical labs are subject to survey requirements but nevertheless believes that the "sheer volume of services and associated billing by these entities" warrants their placement in the moderate risk tier.

CMS considers physicians, nonphysician practitioners, group practices, and medical clinics to present a limited risk of fraud for two reasons—they are state-licensed and the agency has not seen any recent research indicating an elevated fraud risk from this group.

Providers and suppliers that are publicly traded on either the New York Stock Exchange (NYSE) or the National Association of Securities Dealers Automated Quotation System (Nasdaq) are also considered to present a limited risk because of their financial oversight, CMS said.Other limited-risk entities include ambulatory surgical centers, critical-access hospitals, and skilled nursing facilities, according to the proposed rule.

Moderate-risk providers/suppliers include independent clinical labs, nonpublicly traded ambulance service providers, community mental health centers, and comprehensive outpatient rehabilitation facilities. These entities are more dependent on CMS for their salaries and operating expenses and face less oversight than those in the limited-risk category. CMS did acknowledge that independent clinical labs are subject to survey requirements but nevertheless believes that the "sheer volume of services and associated billing by these entities" warrants their placement in the moderate risk tier.

Home-health agencies and durable medical equipment, prosthetics, and orthotics suppliers (DMEPOS) that have not yet enrolled in Medicare are considered high-risk entities, according to the proposed rule. Numerous reports from the OIG and the Government Accountability Office have identified program vulnerabilities within these two categories, leading to their high-risk designation, the proposed rule said.

Application Fees

The proposed rule would require the HHS secretary to impose a fee on all providers/suppliers that would be used to pay for the enhanced screening measures. The fee would apply to all providers billing Medicare, Medicaid,

and CHIP for services, with the exception of Part B medical groups or clinics and physicians and nonphysician practitioners submitting a CMS 855I for enrollment in Medicare.

The fee, to be set at $500, will apply to providers and suppliers enrolling for the first time as well as currently enrolled entities revalidating their status. It will take effect March 23, 2011. For each subsequent year, the fee will be the same as the preceding year, with an adjustment made based on the consumer price index.

The proposed rule also grants the secretary the authority to temporarily suspend enrollment of new providers/suppliers in Medicare, Medicaid, and CHIP, either individually or on a category basis, if a suspension would prevent fraud, waste, or abuse.

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.

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 Code	Procedure Code 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

The self-audit is the result of the department's Laboratory Price Sweeps Special Projects, 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.

News-At-A-Glance

FEDS JOIN SUIT AGAINST MAYO CLINIC: The U.S. Department of Justice has joined a lawsuit against Mayo Clinic that accuses the clinic of submitting fraudulent claims to Medicare and Medicaid for thousands of pathology tests. According to the *Pittsburgh Tribune-Review*, the complaint states that over the course of the last 10 years, Mayo has routinely billed Medicare, Medicaid, and other federally sponsored health care programs for surgical pathology services that have not been performed. The lawsuit was originally filed in November 2007 by attorney and neurologist David Ketroser. The Mayo Clinic has denied the allegations through a statement issued by spokesman Bryan Anderson. "Upon discovering a billing error in 2007, Mayo corrected it and voluntarily refunded $242,711 to the federal government. The error was identified and corrected long before Mayo became aware that a sealed complaint had been filed and well before Mayo was notified that the Department of Justice was evaluating whether to become involved in the complaint. Mayo has fully complied with the law, and we believe our response to the billing error and our approach to surgical pathology represents 'a best practice.' Mayo's strong culture of compliance allowed us to identify the error, correct, and refund the money," the statement said.

OIG ISSUES WORK PLAN: The Health and Human Services Office of Inspector General (HHS OIG) Oct. 1 issued its work plan for fiscal year 2011, indicating that among other activities it will issue reports on trends in laboratory utilization, lab test payments, and laboratory test unbundling by clinical laboratories. In addition, it plans to issue reports on the Food and Drug Administration's 510(k) device clearance process, as well as hospital payments and readmissions. The work plan provides brief descriptions of activities that the OIG plans to initiate or continue with respect to the programs and operations of HHS. For each review, the work plan describes the subject, primary objective, and criteria related to the topic. When reports are issued, they are posted to OIG's Web site. The work plan is available at *www.oig.hhs.gov.*

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