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For Hospitals, Laboratories and Physician Practices

Proposed Medicare Fee Schedule For 2007 Includes Important Changes For Labs

The Medicare physician fee schedule (MPFS) proposal for 2007 contains a host of changes that would affect clinical laboratories and pathologists.

For example, the Centers for Medicare and Medicaid Services (CMS) is proposing tighter curbs on "pod" or "condo" labs, changes to the archived specimens rule, and termination of the grandfather provision affecting the technical component of physician pathology services furnished to hospital patients. In addition, CMS suggests revisions to flow cytometry as well as new requirements for determining payment amounts for clinical laboratory tests.

The proposed changes are contained in a *Federal Register* notice published August 22. CMS will accept comments on the proposed rule until October 22 and anticipates publishing a final rule in November. The final changes would take effect Jan. 1, 2007. ➥ *p. 2*

Inside this issue

FDA Issues Guidance On IVDMI Assays

The Food and Drug Administration (FDA) has issued draft regulatory guidance for a new type of medical test that uses complex mathematical formulas to interpret large amounts of gene and protein data to produce results that can help guide medical decision-making.

These tests, which FDA refers to as in vitro diagnostic multivariate index assays (IVDMIAs), represent some of the most promising developments in diagnostic testing to date, according to the agency. The new guidance is designed to help clarify the agency's regulatory approach to IVDMIAs.

"More and more of these kinds of medical tests are being made available each year," said Daniel Schultz, M.D., director of FDA's Center for Devices and Radiological Health, in releasing the draft guidance. "It is important for the companies and labs making the tests to clearly understand the regulatory requirements in place so that the tests they develop are as safe and effective as possible."

The draft guidance addresses the definition of IVDMIAs and the regulatory rules for companies and laboratories that manufacture these tests. For instance, the guidance says that: ➥ *p. 9*

Medicare Fee Schedule For 2007, *from p. 1*

To curb growth of "Pod" labs, the proposed rule amends the reassignment regulations to provide that if the technical component of a diagnostic test (other than clinical laboratory tests payable under the lab fee schedule) is billed by a physician or medical group under a contractual arrangement, the amount billed is subject to anti-markup rules. It must be the lowest of the net charge to the group, the physician's actual charge, or the fee schedule amount.

For more on the proposed changes, join us on October 10 for a national audioconference: "The Year Ahead: Proposed Changes for Labs & Pathologists in 2007." Details at www.g2reports.com

To bill for the TC, the billing entity would be required to perform the interpretation. CMS also is soliciting comments on whether an anti-markup provision should apply to the reassignment of the professional component of diagnostic tests performed under a contractual arrangement, and if so, how to determine the correct amount that should be billed to the Medicare program.

In addition to the changes to the reassignment rules, CMS is also proposing to change the definition of "centralized building" under the Stark self-referral regulations to include a minimum square footage requirement of 350 square feet. This would be relevant to both the physician services exception and the in-office ancillary services exception and would apply to independent contractor physicians and employed physicians.

The proposed minimum square footage requirement would not apply to space owned or rented in a building in which no more than three group practices own or lease space in the same building.

TC Grandfather Termination

The proposed rule makes clear that CMS intends to terminate the technical component grandfather provisions at the end of this year. In the 2000 physician fee schedule rule, CMS said it would implement a policy to pay only the hospital for the technical component (TC) of physician pathology services furnished to hospital patients. CMS delayed these changes for one year to allow independent laboratories and hospitals sufficient time to negotiate arrangement for services provided by a covered hospital.

Later, full implementation was delayed through this year. As it stands now, after Dec. 31, 2006, an independent laboratory may not bill the carrier for physician pathology services furnished to an inpatient or outpatient. However, legislation pending in Congress would permanently adopt the protection that allows certain "grandfathered" hospitals to contract with pathology labs for the TC of anatomic pathology services provided to hospital patients and permits these contracted labs to bill the Medicare Part B program directly for the TC.

Under the proposed rule, the antibody cost for flow cytometry CPT codes 88184 and 88185 would increase from $3.54 to $8.50. With the scheduled 5.1% reduction in the conversion factor as proposed, 88184 would increase 16% while 88185 would increase 27%.

The "grandfather" protection applies to hospital/lab arrangements in effect as of July 22, 1999, the date when CMS first proposed to end separate Part B payment for the pathology TC services and to require labs to seek reimbursement from the hospital instead.

Physician Fee Cut

The proposed rule projects a 5.1% cut in physician payment for 2007 due to "an increase in the number and complexity of services furnished to Medicare beneficiaries, including more frequent and intensive office visits and rapid growth in the use of imaging techniques, laboratory services, and physician-administered drugs." Many expect that Congress will step in and restore the cut legislatively as they have in the past.

Flow Cytometry

Under the proposed rule, the antibody

cost for flow cytometry CPT codes 88184 and 88185 would increase from $3.54 to $8.50. With the scheduled 5.1% reduction in the conversion factor as proposed, 88184 would increase 16% while 88185 would increase 27%. If Congress acts to freeze the 5.1% reduction and keep the conversion factor at its current level, the increases would be 22% and 33% respectively.

CMS also is proposing a change in the clinical labor type from a laboratory technician to a cytotechnologist and to add more equipment to the practice expense methodology for CPT 88184 and CPT 88185.

Other Changes

Among other changes proposed in the MPFS rule:

- **Payment for new tests.** CMS is proposing new requirements for determining payment amounts for clinical laboratory tests assigned a new or substantially revised code on or after Jan. 1, 2005. Specifically, CMS intends to add a new section to indicate when crosswalking or gap-filling may be used.
- **Quality.** CMS says it is exploring the development of measures related to the quality and efficiency of care, including those involving clinical laboratory fee schedule services. One possibility is requiring those who perform lab tests to submit lab values using common vocabulary standards, such as those found in the Logical Observation Identifiers Names and Codes (LOINC) database. CMS says it plans to work collaboratively with the clinical laboratory community on these efforts.
- **Blood glucose monitoring in SNFs.** CMS is reiterating its longstanding policy on coverage of blood glucose monitoring services in skilled nursing facilities (SNFs): To be considered reasonable and necessary, the test must be ordered by the physician and the ordering physician must use the result in the management of the beneficiary's specific medical problem. CMS is proposing to codify physician certification requirements for blood glucose monitoring in SNFs: Physicians must certify that each test is medically necessary and a standing order is not sufficient to order routine blood glucose monitoring.

Resource

- Aug. 22, 2006, *Federal Register*: www.archives.gov/federal-register/index.html

OIG Publishes Guidelines For State False Claims Acts

Effective Jan. 1, 2007, states that meet certain requirements established by the Department of Health and Human Services Office of Inspector General (OIG) will be allowed to retain 10% of the federal share of Medicaid fraud recoveries.

Under the federal False Claims Act (FCA), any person who knowingly submits a false or fraudulent claim to a state Medicaid program is liable to the federal government for three times the amount of the damages plus penalties of $5,000 to $10,000 for each false or fraudulent claim.

Currently, any recovery of damages to the state Medicaid program will be shared with the state in the same proportion as the state's share of the costs of the Medicaid program. For example, if a state's Medicaid share is 40%, then the state would be entitled to receive 40% of the damages and the federal government would retain 60% of the damages.

The Deficit Reduction Act of 2005 (DRA), however, creates a financial incentive for states to enact their own false claims legislation that is at least as tough as the federal law. Starting Jan. 1, 2007, a state with a law in effect that meets the requirements

below will qualify for a 10% increase in its share of any amounts recovered from a state action brought under the law.

The state law must:

1 Establish liability to the state for false or fraudulent claims as described in the Social Security Act;

2 Contain provisions that are at least as effective in rewarding and facilitating qui tam actions for false or fraudulent claims as those described in the federal False Claims Act;

3 Contain a requirement for filing an action under seal for 60 days with review by the state attorney general; and

4 Contain a civil penalty that is not less than the amount of the civil penalty authorized under the federal FCA.

The OIG will accept requests for review of state laws to determine if they meet these requirements. To request review, the state Attorney General's office should submit a complete copy of the law to the OIG, Cohen Building, Mail Stop 5527, 330 Independence Ave., SW, Washington, DC 20201. Attn: Roderick Chen, Office of Counsel to the Inspector General.

Resource

- Aug. 21, 2006, *Federal Register*: www.archives.gov/federal-register/index.html

More False Claims Act Recoveries Involve Health Fraud

In 2005, $1.1 billion, or 79% of the more than $1.4 billion recovered by the government from False Claims Act (FCA) qui tam actions, involved healthcare fraud, according to a Department of Justice (DOJ) official.

Speaking at a Taxpayers Against Fraud Education Fund Conference in Washington, D.C., Joyce Branda, deputy director of the fraud section in the Department of Justice Civil Division's Commercial Litigation Branch, told participants that the United States recovered more than $9.6 billion from FCA qui tam actions from 1986 through 2005 and recovered a total of more than $15 billion from both FCA qui tam actions and nonqui tam actions. As a result of the $9.6 billion in qui tam action recoveries, whistleblowers received shares of more than $1.6 billion, Branda said.

According to U.S. Attorney for the District of Massachusetts Michael Sullivan, in fiscal 2006 DOJ recovered more than $2.3 billion in just three settlements, making this year the most effective so far for recoveries.

"Every dollar spent by the government returns more than $15 in FCA recoveries," Sullivan said at the September 12 conference. "Of the $3 billion Massachusetts recovered from healthcare fraud in the last five years, $1 billion was recovered in the last year alone."

DOJ's priorities in its healthcare fraud investigation recently have focused on the pharmaceutical industry. To date, the government has recovered $4.5 billion in fines. The agency also is examining quality care issues in long-term care facilities and cost report fraud and upcoding in hospitals.

Schering-Plough To Pay $435 Million In Settlement

Schering-Plough Corp. and its subsidiary Schering Sales Corp. have agreed to pay a total of $435 million to resolve criminal charges and civil liabilities stemming from the illegal sale and marketing of the certain drugs, U.S. Attorney for the District of Massachusetts Michael Sullivan announced August 29.

The agreement involves Schering Sales pleading guilty to one count of criminal conspiracy to make false statements to the Food and Drug Administration about promotional activities for the drug Temodar and Intron A and to the Health Care Financing Administration (now called the Centers for Medicare & Medicaid Services) about its Medicaid best price for Claritin RediTabs, according to a statement from Sullivan's office.

As a result, Schering Sales will be excluded permanently from participating in Medicare, Medicaid, and other federal healthcare programs, and will pay a $180 million criminal fine.

COMPLIANCE PERSPECTIVES

Important FAQs About Slide Consult Coding & Billing

Dennis Padget is president of DLPadget Enterprises Inc., publisher of the comprehensive business guide Pathology Service Coding Handbook

Myths and misconceptions abound about the proper CPT reporting and third-party billing rules for pathologist consultation services described by codes 88321, 88323, and 88325. The following FAQs (frequently-asked-questions) set the record straight regarding several such issues. The CPT procedure descriptors considered herein are 88321, *Consultation and report on referred slides prepared elsewhere*; 88323, *Consultation and report on referred material requiring preparation of slides*; and 88325, *Consultation, comprehensive, with review of records and specimens, with report on referred material*.

1 I just received a request from a surgeon not on staff at my hospital to send slides from a recent biopsy to an outside pathologist for confirmation review. Can I charge a handling fee to recover the time and expense I'll incur responding to this request?

The chances of a pathologist or lab collecting a handling fee in this situation are so small that few bother even trying. Custom directs that the requesting physician or hospital not be charged for your processing and shipping costs. CPT provides two lab specimen handling/conveyance codes (see 99000 and 99001 in your codebook) that might be reported, but it's the rare insurer that covers them. Most insurers emulate Medicare on handling fees: Those costs are part of the test or consult, so a separate charge can't be billed to the program or the beneficiary.

2 A former patient or her outside specialist wants another pathologist to confirm my diagnosis. Am I or my hospital liable for the outside pathologist's consultation fee?

No, at least not according to general business theory. You didn't request the consult, nor will you likely benefit from it. Therefore, responsibility for paying the outside pathologist falls on the patient, not you or your hospital.

3 I'm not 100% comfortable with the diagnosis for a biopsy that just came in. If I send the case out for second/expert opinion, am I responsible for the outside consultant's fee, or can the patient or his insurer be billed?

The answer depends on the dominant rationale for the second opinion. Sometimes you'll send out a case "just to be sure"—you're not really all that uncomfortable with the diagnosis, but it's nice to have a second pair of eyes look at the slides. This consult isn't "medically necessary" from a third-party payer perspective, so you or your hospital should absorb the consultant's fee as part of your ongoing quality assurance program.

At other times there's genuine uncertainty as to the most accurate diagnosis, or the case may present ambiguous findings best resolved by a specialist. In these instances appropriate patient care basically demands that a second or expert opinion be sought. It's very unlikely that at any time you promised someone—either expressly or implicitly—that you'll personally render the final, definitive diagnosis on every case that comes your way. Therefore, when you request an out-

side consultant's opinion in this context, his or her fee is chargeable to the patient or third-party payer as a medically necessary service.

Some people suggest that, for an outside consult to be patient/insurance billable, you must get the patient's and/or the attending physician's concurrence regarding medical necessity. (See, for example, the CPT reporting advice given on page 128 of the July 2006 issue of *CAP Today*.) While patient relations and professional courtesy may promote such communication, applicable federal law and regulation leave the medical-necessity decision solely in the responsible pathologist's hands.

4 The outside pathologist I often use for second/expert opinion cases refuses to bill patients or insurers; she insists that I or my hospital pay her fee immediately upon receipt of the invoice. Can I or my hospital pass the consultant's charge along to the patient or the insurance company, assuming the consult was medically indicated in the first place?

The answer depends largely on the payer or insurer involved. If the patient is a Medicare beneficiary, it's almost assured that neither you nor the hospital may legally collect the consultant's professional fee as a pass-along charge to the program or the patient. That's because, in all likelihood, neither you nor the hospital retains the consultant as an independent contractor, has a written reassignment from the consultant giving you the right to bill Medicare for his or her services, has filed Form CMS-855R with the local Part B carrier setting up the consultant as a physician for whom you're permitted to bill, or complied with the other program reassignment requirements.

(Pathology consult codes 88321-88325 appear in Medicare's Outpatient Prospective Payment System fee schedule as payable services to hospitals for outpatients. The problem is a physician professional fee is converted to a hospital technical charge if the hospital bills one of these codes to the Part A fiscal intermediary, and some authorities believe that's tantamount to filing a false claim. Besides, the 88321 code pays less than 10% of the amount consultants often charge, so it's hardly worth the risk. Hopefully the Centers for Medicare and Medicaid Services will one day explain why these codes are in the OPPS fee schedule, and we'll then know for sure whether or not we can properly use them.)

If the patient is covered by Medicaid, there's a good chance the consultant won't be able to collect from the program, because quite a few agencies refuse to pay out-of-state physicians who aren't credentialed in-state. Whether your Medicaid agency will let you or your hospital recover at least part of the consultant's fee by posting an 88321-type charge to your claim is something you'll have to determine from its coverage policy and billing guide.

Private insurers usually aren't as restrictive as Medicare and Medicaid when it comes to passing along an outside physician's charge on your claim. In fact, out-of-network terms and credentialing provisions may prevent the consultant from directly billing some private insurers. You typically have to determine what will and won't work on an insurer-by-insurer basis, but, in general, your hospital likely will have a far easier time collecting a pass-along consulting fee from a private insurer than you will billing as a physician.

In general, consultants typically charge more than most insurers are willing to pay, so from a prudent-buyer standpoint you'll probably want to send your cases to outside pathologists who agree to bill patients and insurers whenever feasible. At a minimum, you should insist that the consultant directly bill Medicare for services to beneficiaries.

5 I sometimes pull patient slides from archives and review them in conjunc-

tion with the current biopsy. Once in a while I have to get past slides from an outside hospital or lab to correlate with the current specimen. Can I charge an 88321-type consult fee in addition to the regular gross and microscopic code in these instances?

You can't consult with yourself, so there's basically no scenario under which you can bill an 88321-type code for reexamining past slides you or one of your associates diagnosed way back when. For much the same reason payers will look askance at such a charge if you unilaterally initiate the request for outside slides and/or blocks.

It's conceivable that the patient's attending physician will specifically ask you to reexamine old or outside slides—you might even prompt the request by explaining to the attending why such a reexamination is in the patient's best interests in a particular instance. A documented request from the attending physician ordinarily will support your reporting clinical pathology consultation code 80500 for in-house archive slides or 88321 for outside slides. (See 80502, 88323, and 88325 for possible—but unlikely—alternate codes.) A distinct consultation finding must be reported to the attending physician either as a separate document or a unique part of the pathology report. Experience indicates situations like this when a separate charge is justified are few and far between.

6 The other pathologists in my group and I often look at one another's slides, and sometimes a diagnosis is changed or clarified based on that second look. Can we charge an additional 88321 code for consulting with one another, or are we limited to just the regular gross and microscopic charges?

So-called "intra-group consultations" almost always form an integral part of an ongoing quality assurance or quality control program for a practice; hence, a separate consultation fee generally can't be claimed case-by-case. Nonetheless, provision is made for 88321-type consultation fee billing when certain rigid—and typically unique—circumstances are encountered. In the main, the consultation must be bona fide, the consultant must be recognized by and receive cases for consultation from outside pathologists, a separate consultation report must be issued, and the consultant and his or her referring associate can't regularly practice at the same site. You're advised to work closely with legal or other expert counsel before starting to charge for consults between members of the same practice, if you think your group qualifies.

7 Today I received slides for a patient from two different cases (S-06-1449 and S-05-12255), and the referring pathologist wants my expert opinion on the diagnosis. The first case consists of four distinct specimens, and the second has 12 parts. I'll individually diagnose each specimen (16 total) in my consultation report. Do I charge 88321 times one, two, 16, or what?

The approved unit of service for consultation codes 88321-88325 is the "outside case"; the number of individual specimens isn't relevant, nor is the fact that you issue only one report. In this instance, report code 88321 times two.

8 Case S-05-12255 in the preceding vignette covered more than 60 slides that had to be individually examined and considered in the diagnosis. Can I report comprehensive consult code 88325 for it under the circumstances? After all, I did receive the outside pathologist's initial report.

Absolutely not! The American Medical Association (AMA) and the College of American Pathologists (CAP) are adamant that code 88325 can be reported only if extensive medical documentation beyond the initial pathology report is received and considered in the overall diagnosis. The number of slides, individual specimens, minutes or hours to work up

the case, etc. aren't influential in these regards. Beware the consultant who frequently reports 88325 for his or her cases!

9 I usually order immunohistochemistry stains in-house on the blocks I receive for consultation from outside hospitals. However, the outside H&E slides usually are adequate. The IHC slides are used to augment the outside H&E slides. Can I charge code 88323 in these instances?

No. Information from the AMA and CAP suggests code 88323 applies only when the consultant orders added routine preparations for direct microscopic examination, such as when deeper sections are required or when the original H&E slides are suboptimal in some way. If added slides are made from the block solely as the foundation for special studies, the basic consult code stays at the 88321 level; of course, you add the appropriate special study code (e.g., 88342) just as you would on an in-house patient case.

10 Immunohistochemistry or other special stain slides sometimes come to me together with H&E slides for examination and consultation. Can I charge separately for examining the special stains like I do for in-house patient cases?

No. The coding authorities indicate that base consultation codes 88321-88325 cover all the preparations that come with the case and that were developed outside the consultant's lab. Hence, if you receive 10 H&E slides, six IHC slides, four fungal stain slides, and an electron micrograph for examination with an outside case, report everything under a single 88321 code, assuming the initial pathology report is the only other material received from the referral source. On the other hand, if you have to repeat a stain in-house due to poor quality (for example) or perform a stain in-house that wasn't done at the outside lab, then you can add the appropriate special study code (e.g., 88342) to the base code.

11 My hospital wants to charge a technical fee in conjunction with the outside consult cases I receive. Is that permitted?

Not unless you order additional routine preparations (e.g., H&E slides) for direct microscopic examination, as for deeper sections, for example. The Medicare physician service fee schedule applies to your outside consult cases because the patients are neither inpatients nor outpatients *of your hospital*, even though they may well have been registered at another hospital. That fee schedule doesn't accommodate a technical component for consultation codes 88321 and 88325, so your hospital's charge will be denied as a duplicate of yours, or as not permitted for the type of provider that's billing. Either way, a technical component isn't recognized.

To the contrary, code 88323 has a distinct technical component attached to it in Medicare's physician service fee schedule, so your hospital is fully entitled to report it on a Form CMS-1500 claim filed with the Medicare Part B carrier when the circumstances warrant. Modifier TC must be appended to denote that only the technical component is being billed by the hospital. Report code 88323 only when the added routine slides (e.g., H&E preparations) are ordered for direct microscopic examination, not merely as the basis for a special study.

Your Medicaid agency and the private insurers you deal with may or may not be as limiting as Medicare when it comes to reporting a technical charge for consult codes 88321 and 88325. However, in general, it's recommended that hospitals forego a technical fee on outside consult cases, except in valid 88323-type service situations.

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FDA Guidance, *from p. 1*

- IVDMIAs employ an algorithm, a specified procedure to solve a problem, to evaluate patient test results along with other clinical information for use in the diagnosis of a disease or condition, or in the cure, mitigation, treatment, or prevention of disease;
- Examples of IVDMIA tests include those used to diagnose and guide treatment decisions for breast cancer, prostate cancer recurrence, cardiovascular disease, Alzheimer's disease, and many other complex common diseases; and
- FDA classifies an IVDMIA based on its intended use and on the level of control necessary to assure the safety and effectiveness of the device. Most IVDMIAs fall under moderate-risk (class II) or high-risk (class III) categories.

"We welcome the opportunity to participate in shaping regulatory policies moving forward by providing comment on this draft guidance and encourage all stakeholders, including physicians and patients, to do the same."
—Randy Scott, Genomic Health

Opportunity To Shape Policy

Randy Scott, Ph.D., chairman and CEO of Genomic Health Inc. (Redwood City, CA), notes in a statement that the FDA's draft guidance represents the first public discussion surrounding the agency's thinking about the regulation of certain laboratory-developed (often called "home brew") tests.

"We welcome the opportunity to participate in shaping regulatory policies moving forward by providing comment on this draft guidance and encourage all stakeholders, including physicians and patients, to do the same," he says.

Genomic Health plans to continue its ongoing dialogue with FDA regarding Oncotype DX, which has been shown to predict the likelihood of cancer recurrence and chemotherapy benefit in early-stage breast cancer patients. Oncotype DX, which went through multiple clinical trials involving 2,600 patients, became commercially available in 2004. Since then, more than 3,400 physicians have ordered a total of more than 15,000 tests services for their breast cancer patients.

Resources

- *Federal Register* notice: www.fda.gov/OHRMS/DOCKETS/98fr/ch0641.pdf
- Randy Scott, Genomic Health: 650-569-2281

CMS Considers Part D Plans' Oversight Responsibilities

The Centers for Medicare and Medicaid Services (CMS) is weighing how responsible Part D plans should be for ensuring regulatory compliance by their subcontractors, a Medicare official said September 11.

Greg Jones, in CMS's Program Integrity Group, told the Health Care Compliance Association's Medicare Prescription Drug Part D Compliance Conference that he is looking at how and where to draw the line regarding plans' responsibility for contractors.

Insurers are questioning how broadly they must interpret fraud, waste, and abuse guidance in the CMS's Part D manual (commonly referred to as chapter 9 guidance). The guidance relates to their responsibilities for ensuring compliance with Part D regulations and applicable Medicare laws among their subcontractors.

Jones likened the concerns to those posed to the Department of Health and Human Services Office of Inspector General regarding compliance training requirements for all "covered persons," saying healthcare organizations were concerned they would be required to provide compliance training to all company employees.

Levinson Calls MMA, DRA Challenging Times For OIG

Daniel R. Levinson

Two years and two major healthcare laws later, Daniel R. Levinson is leading the Department of Health and Human Services' chief law enforcement agency through what he calls challenging and exciting times.

"These are important days here," Levinson says, as he talks about the expertise the Office of Inspector General's staff brings to new agency responsibilities under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and the Deficit Reduction Act of 2005.

Both laws mandated new responsibilities for the OIG, some reflecting the agency's chief historic duty of rooting out fraud and abuse in the Medicare program, while others are requiring new skills.

Yet, Levinson says, the OIG staff is well equipped to meet the challenges of new work, and already is proving it is up to the tasks.

Building Relationships

Central to his office's success in meeting congressional mandates in MMA and DRA, he says, is forging relationships with partner agencies—Department of Justice, Centers for Medicare & Medicaid Services, Food and Drug Administration, Social Security Administration, and Department of Labor.

Although the OIG already worked closely with most, if not all, of those agencies, Levinson says MMA brought a greater need to ensure strong partnerships with other "key" players in implementing the Part D program.

In particular, OIG worked with CMS, DOJ, and others on what Levinson calls a "robust" training agenda, in part to evaluate the vulnerabilities of the program and identify enforcement areas.

Ongoing efforts also have meant Levinson has been on the road often, meeting with regional OIG personnel around the country as well as members of the DOJ healthcare fraud task force, U.S. attorneys, and CMS staff.

He says he is taking the same approach to new OIG responsibilities under DRA, undertaking a vigorous travel schedule to meet with Medicaid Fraud Control Unit directors and deputy attorneys general about Medicaid fraud provisions.

Again touting the need for strong relationships with other agencies, Levinson says that a key role for the OIG will be organizing a major training effort in the fall with MFCUs, DOJ personnel, CMS, and others at the National District Attorneys Association National Advocacy Center on the University of South Carolina campus in Columbia, South Carolina.

Levinson says the first-of-its-kind comprehensive training will focus on Medicaid issues, including new DRA requirements, and will be an opportunity to discuss how OIG and others will be more active in Medicaid fraud fighting and program oversight.

State False Claims Laws

Levinson also discussed OIG guidance for states planning to enact state false claims laws as prompted by incentives in DRA.

The DRA provisions, crafted by Senate Finance Committee Chairman Charles E. Grassley (R-Iowa), would allow states to retain 10% of the federal share of Medicaid fraud recoveries if they enact state-based false claims laws at least as effective as the federal False Claims Act (*see related article on pg. 3*).

OIG, along with DOJ, was charged in DRA with determining on a case-by-case basis whether states' laws met the effectiveness test to qualify for the incentive.

Although Levinson says the expected proliferation of state laws will add an

"important and extra dimension" to Medicaid fraud-fighting efforts, he does not expect the new laws to change the landscape of federal False Claims Act investigations and enforcement.

"I think the office will be very interested in following those developments," he says, largely because the Medicaid share of cost recoveries has been outpacing the growth of Medicare recoveries in recent years.

"I don't think a few years ago people would have expected that," Levinson says.

Drug Pricing

The DRA provisions come as the OIG is settling into new Medicare Part B drug pricing responsibilities mandated in MMA.

Levinson says that while drug-pricing mandates—such as a recent OIG report comparing average sales prices for Part B drugs to the prices widely available to physician purchasers – are a new area for the OIG, the agency builds on a clear area of expertise among its personnel.

"In that respect, the transition has been easy," he says, noting that past audits, evaluations, and inspections work were good preparatory skills for conducting the drug pricing work. "Some of those areas are fresh," he says, "but we're experts certainly in fraud."

That expertise was easily translated to Part D oversight work, Levinson explains, citing several investigations already under way in the Medicare drug program.

Among them, he says, are cases involving marketing and enrollment fraud in which insurance marketers allegedly enrolled Medicare beneficiaries into Medicare Advantage plans when they believed they were being signed up for standalone prescription drug plans.

The OIG is also looking at how some marketers obtained beneficiary information to make unsolicited marketing calls, Levinson adds.

Also being investigated is a Part D-participating pharmacist who allegedly bought back drugs for restocking purposes and a pharmacist at a large retail pharmacy chain who allegedly substituted generic drugs for Part D enrollees but billed for the more expensive brand equivalents, Levinson says.

Mandated Funding

When yearly increases in OIG funds under the Health Insurance Portability and Accountability Act (HIPAA) leveled off in 2003, there was concern among some industry experts whether the OIG would be able to continue the same level of work it had produced in the past, much less take on new responsibilities.

However, Levinson says Congress recognized, in both the MMA and DRA laws, that OIG needed additional resources to take on new duties, calling it important and helpful that both laws came with $25 million boosts in funding.

"The MMA add-on has been key to getting off to a healthy start," he says. "We have retained a solid base of expertise. We have people who are the best in the business."

The funding cap in 2003 had put the OIG in a shrinking, or at least standing-still, position, Levinson says, but that has changed. "We're not in a shrinking mode at all," he says.

Even with new duties, Levinson says, the OIG's traditional level of work, including pharmaceutical fraud cases, will always be part of the OIG's mission. "That work will really remain core," he says. "The kinds of work we've done in years past, we don't see going away."

Nevertheless, he says he is reluctant to talk about trends in healthcare fraud.

"We treat each case as an individual case," Levinson says. "That's the nature of the work we do."

OIG Guidance: The association representing the medical device industry on September 6 asked the Department of Health and Human Services Office of Inspector (OIG) for guidance on compliance of the anti-kickback statute by physicians investing in medical device companies. The letter from Advanced Medical Technology Association (AdvaMed) focuses on the emergence of medical device companies in which physicians have an equity ownership interest and generate a substantial portion of the companies' revenues—more than 40%. This recent development in the device industry raises important legal and policy issues relating to the potential effect on physicians' clinical decisions that may be inconsistent with the goals of the anti-kickback statute, the letter said.

Glaxo Settlement: GlaxoSmithKline has agreed to pay $70 million under the terms of a nationwide class-action settlement to resolve claims that it artificially inflated the prices of drugs, including medications for cancer patients. The company said the accord settles all claims regarding the average wholesale price (AWP) of certain pharmaceuticals. The claims were filed against GlaxoSmithKline in consolidated multidistrict litigation pending in federal court in Boston. The settlement will provide reimbursement to both patients and third-party payers, such as union benefit funds and health plans.

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