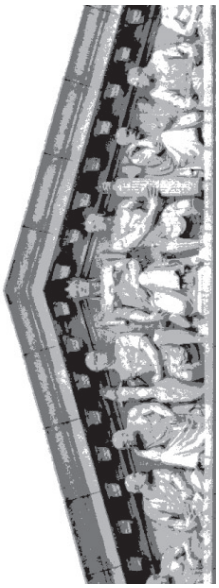

G-2 Compliance Report

WASHINGTON G-2 REPORTS

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For Hospitals, Laboratories and Physician Practices

Giving Free Blood Collection Supplies To Docs Raises Kickback Concerns, Says OIG

A clinical laboratory's proposal to provide free blood collection supplies to physicians and pay those physicians for the collection of blood samples could potentially violate the anti-kickback statute, concludes the Health and Human Services Office of Inspector General (OIG) in an advisory opinion released June 13 (No. 05-8).

The lab requesting the opinion, which is unidentified, currently performs blood draws and laboratory tests on-site. However, some of the referring physicians have told the lab that they would like to draw their patients' blood during office visits, rather than send their patients to the lab for blood draws, and have the lab pick up the specimens from the physicians' offices. These physicians have requested that the lab provide blood drawing supplies at no charge to the physicians and pay the physicians a per-patient amount for the physicians' services in collecting the blood specimens (the "blood draw remuneration").

Medicare pays $3 per patient encounter for specimen collection fees charged by physicians, independent laboratories, or hospital laboratories for the services and supplies they use in collecting blood samples, payable only to the person or entity that actually extracted the specimen from the patient.

Under the proposed arrangement, the amount the lab would pay to each physician would be determined according to negotiations between the lab and physician, ➥ *p. 2*

PA Hospital To Pay $4.2 Million In Lab Billing Settlement

Abington Memorial Hospital in Philadelphia has agreed to pay the federal government $4.2 million to settle allegations that it submitted more than 70,000 false claims for clinical laboratory tests to Medicare over a nine-year period, according to the U.S. Attorney's Office for the Eastern District of Pennsylvania. The settlement resolves a civil action filed against the hospital in April 2003.

Richard Jones, president of Abington Memorial, said that the hospital did not admit guilt, but agreed to the settlement to avoid the time and expense of litigation. "Abington Memorial Hospital denies any intention of wrongdoing in the disputed claims," he said in a statement. "The mistakes made were the result of human error in a complex billing system that includes tens of thousands of billing codes, with complicated and ambiguous guidelines."

False Claims Violations

Federal prosecutors alleged the hospital's submission of certain ➥ *p. 9*

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Kickback Concerns, *from p. 1*

but would likely be between $3 and $6 for each patient receiving a blood draw, although the payment would be made no more than once each day for each patient. The lab states that it wishes to enter into the proposed arrangement because competing laboratories are paying referring physicians to perform blood draws.

OIG Response

According to the OIG, the proposed arrangement would "clearly" implicate the anti-kickback statute. "There is substantial risk that the lab would be offering the blood draw remuneration to the physicians in exchange for referrals to the lab," the OIG writes in the advisory opinion, noting that physicians could receive up to twice the $3 amount Medicare pays for blood specimen collection, plus any necessary blood-drawing supplies free of charge.

"Particularly when viewed in the aggregate, this compensation provides an obvious financial benefit to the referring physician, and it may be inferred that this benefit would be in exchange for referrals to the lab," says the OIG. "Where a laboratory pays a referring physician to perform blood draws, particularly where the amount paid is more than the laboratory receives in Medicare reimbursement, an inference arises that the compensation is paid as an inducement to the physician to refer patients to the laboratory, particularly in the circumstances presented here."

Further, the proposed arrangement essentially would give the physicians the opportunity to earn a fee otherwise earned by the lab, according to the OIG. Because the physicians would receive a portion of the lab's reimbursement for blood tests resulting from the referrals, the physicians have a strong incentive to order more blood tests, the OIG adds.

"As a result, there is a risk of overutilization and inappropriate higher cost to the federal healthcare programs," the agency writes. "We discern no safeguard in the proposed arrangement to rebut the inference or reduce the risk that the blood draw remuneration would be intended to induce referrals."

In addition, the OIG says that any specimen collection claims submitted by the lab to Medicare for blood draws performed by the referring physicians would be improper claims and would implicate the federal False Claims Act. Medicare pays only the person or entity that actually extracted the specimen from the patient. While, under some conditions, physicians can bill Medicare directly for collecting blood specimens, if the lab were to pay a physician to perform a blood draw, the physician would be impermissibly "double dipping" if he or she also billed Medicare for that blood draw.

According to the OIG, physician charges for specimen collection are allowed when: 1) it is the accepted and prevailing practice among physicians in the locality to make separate charges for drawing or collecting a specimen; and 2) it is the customary practice of the physician performing such services to bill separate charges for them.

Resource

❖ OIG advisory opinion No. 05-8: *www.oig.hhs.gov*.

MDS Reaches Settlement Over Billing Errors

MDS Diagnostic Services (Toronto) has reached an agreement with the New York Attorney's office to resolve billing errors caused when its former business, MDS Hudson Valley Laboratories, changed computer billing systems. Only patients of MDS Hudson Valley Laboratories residing in New York state were affected.

Under the agreement, MDS will provide refunds to New York consumers improperly billed for services covered by their health plans. The company also agreed to reform its billing practices so that, when it submits a claim to a health plan, it will not bill consumers until it receives notification from the plan that the consumer may be liable for the payment.

An estimated 2 million claims could be subject to terms of the agreement, which is the latest in an initiative launched by New York Attorney General Eliot Spitzer (D), dubbed Project Clean Bills of Health. The project has already yielded settlements with Quest Diagnostics, Vineall Ambulance Co., and WellCare of New York.

Pathologists Continue Fight Over PC Reimbursement

Jane Pine Wood, Esq.

Pathology groups across the country are continuing to fight with insurers over denial of reimbursement for the professional component (PC) of clinical pathology services. The latest battle involves Ingenix, an affiliate of United Healthcare (UHC), according to Jane Pine Wood, an attorney in the Cleveland office of McDonald Hopkins Co., which represents many of the pathology groups.

A number of insurers, including UHC, Blue Cross, and Aetna, have taken the position that they follow Medicare guidelines when paying for the PC services (*GCR,* February 2005, p. 1). Medicare generally provides for professional component reimbursement through Part A hospital payments and does not make a separate payment to pathologists.

However, groups representing pathologists note that private insurers have no analogous payment mechanism, and many of these payers' contracts with hospitals and pathologists do not support the position that the payers include payment for the PC services in their payments to hospitals, notes Wood.

Pathologists nationwide stand to lose millions of dollars.

While the American Medical Association (AMA) wrote a letter in December 2004 to UHC arguing the insurer's policy change is contrary to CPT guidelines concerning modifier –26, the insurer and its subsidiaries are continuing to deny payment, or, in some cases, are negotiating payment on an individual basis, says Wood. As a result, pathologists nationwide stand to lose millions of dollars.

In a more strongly worded letter sent to Ingenix on June 23, 2005, AMA Executive Vice President and CEO Michael Maves, M.D., wrote that the AMA has received complaints regarding Ingenix's position on the use of the modifier –26 to report the professional component of pathology and laboratory services. "We disagree with your opinion that a written report must be generated by the pathologist in order to append the professional component modifier to pathology and laboratory CPT codes," Dr. Maves wrote.

"From a CPT coding perspective, the use of modifier –26 is required for pathology and laboratory codes 80049-87999 when the physician is reporting only the professional component of laboratory tests," Dr. Maves continued.

"Specifically for pathology and laboratory services, the modifier –26 can be used for medical direction, supervisions, and/or interpretation for all laboratory CPT codes. This has always been the AMA's opinion and has been published in the May 1999 *CPT Assistant* newsletter. In using modifier –26 for pathology and laboratory codes 80049-87999, a written report for an individual patient is not a requirement for having performed a professional component service since it can be reported for medical direction of the tests performed."

Dr. Maves urged all third-party payers who use code-editing software and vendors of claims editing software to ensure that CPT codes, guidelines, and conventions contained in the annually revised CPT publications are followed on a consistent basis. Diligent adherence to these guidelines preserves the integrity of CPT coding and maintains the efficiency of healthcare delivery that all patients deserve, he said.

"Based on the information provided above, we trust that Ingenix will immediately change its practice of rejecting accurately coded physician claims when the appropriately designed CPT codes and modifiers are reported," Dr. Maves wrote.

Wood says Ingenix has not yet responded to the AMA letter. Meantime, McDonald Hopkins is continuing to contemplate legal action against the insurers, although the firm would prefer to resolve the issue without going through the courts. "We're still hoping that the insurers will come around," notes Wood.

Resources

❖ Jane Pine Wood: 508-385-5227

OIG Proposes New Safe Harbor On Financial Links

The Department of Health and Human Services Office of Inspector General (OIG) has proposed new standards for an anti-kickback safe harbor that would protect certain financial arrangements between public health centers and other healthcare providers and suppliers.

Under the proposed safe harbor, goods, items, services, donations, or loans must contribute to the health center's ability to maintain or increase the availability, or enhance the quality, of services available to a medically underserved population. Comments on the proposal, contained in the July 1 *Federal Register*, are due by August 1.

Congress mandated the safe harbor in the Medicare Modernization Act of 2003 in response to concerns from providers that financial arrangements with public health centers could implicate the anti-kickback statute. Safe harbors exempt certain remuneration and arrangements from scrutiny under the anti-kickback statute, provided certain specific conditions are met.

Among the requirements proposed by the OIG to meet the safe harbor: Arrangements must benefit health centers directly, not the individual or entity providing the remuneration; arrangements should not limit patients' freedom to choose services from any provider or supplier; and arrangements should not improperly steer clinical decisions based on financial interests.

Public health centers are funded with federal Public Health Service (PHS) grants. However, health centers often seek out, or are offered opportunities to enter into, arrangements with hospitals, care providers, and suppliers to enhance or improve patient care consistent with the PHS mission.

However, there has been concern among providers and suppliers that these arrangements may be suspect under the anti-kickback statute because the health centers often are in the position to refer patients covered by other federal health programs, such as Medicaid.

Resources

- July 1 *Federal Register* notice: *www.oig.hhs.gov/authorities/docs/05/070105NPRM-FQHC.pdf*

Daniel Levinson Sworn In As HHS IG

Daniel Levinson was sworn in as Inspector General of the Department of Health and Human Services (HHS) June 9 after Sen. Frank Lautenberg (D-NJ) released a hold he placed on the nomination.

President Bush nominated Levinson for the post in July 2004, and the Senate Finance Committee approved the nomination on March 17, 2005. But Sen. Lautenberg stalled further action in an effort to push HHS to pursue action against Thomas Scully, the former head of the Centers for Medicare & Medicaid Services (CMS), for pressuring an actuary to withhold cost estimates for the Medicare drug benefit from lawmakers in 2003.

Sen. Lautenberg released the hold after Levinson had satisfactorily answered questions Lautenberg posed to him about resolving the Scully matter.

A report by the Government Accountability Office (GAO) in 2004 recommended administrative action against Scully for threatening disciplinary action against CMS actuary Richard Foster if he shared higher-than-previously-reported cost estimates for the Part D drug benefit while lawmakers were considering passage of the Medicare Modernization Act of 2003.

Among remedies GAO suggested was recovering salary payments to Scully because his actions barring Foster from sharing information with Congress violated the Consolidated Appropriations Act of 2003.

That law prohibits using appropriated funds to pay salaries of officials who prohibit another federal employee from communicating with Congress about agency-related matters.

COMPLIANCE PERSPECTIVES

Tips For Minimizing Pathology & Lab Charge Denials

Dennis Padget is President of DLPadget Enterprises, Inc., a pathology and laboratory business research and publishing company in Simpsonville, Kentucky

Charge denials cost big bucks. Even if you eventually get paid, handling all that extra paper cuts into your profit margin. Everybody strives for "clean" claims, but with new National Correct Coding Initiative (NCCI) and other edits coming out all the time, how do you manage to keep up so you can handle accounts only once?

This article won't solve all your problems, but it will help reduce the number of denials you've been getting lately. It also explains how to stem your losses on several key service scenarios hard hit by recent coding edits or other barriers.

Match Those PC & TC Codes

Medicare contractors and private insurers are gaining ground in their ability to compare hospital technical and physician professional charges. Claims can be suspended while a discrepancy in reported CPT codes or units of service is investigated. Alternatively, a charge or two might be summarily denied when the professional and technical codes don't fall in the same CPT family like they're supposed to—a discrepancy that affects independent labs as well.

Nearly every pathology CPT code has a professional and a technical component, in the sense that the same codes appear on Medicare's physician and hospital fee schedules (RBRVS and Outpatient Prospective Payment System—OPPS—respectively). Even codes that might seem to be physician-only services are valid for OPPS payment; for example, see 80500/80502 (clinical pathology consults), 85060 (abnormal peripheral blood smear review), 86077-86079 (physician blood bank services), and 88329 ("gross only" intraoperative consult). With rare exception, for each pathologist professional charge, there should be a hospital technical charge.[1]

Hospitals and their pathologists should use a charge assignment system that ensures congruence of technical and professional procedure codes on their separate claims. Many hospitals wait to get their technical codes from the pathologist, who selects the professional codes based on the final medical report. However, a knowledgeable hospital coder always reviews the pathologist's charge determinations in light of the lab record, and any difference in judgment is reconciled before either party releases a claim. A hospital shouldn't assign its histology technical codes based solely on the requisition: Such a system is guaranteed to generate technical/professional charge discrepancies, and the hospital's legitimate revenue will be understated by a significant percentage.

A variation on the PC/TC charge matchup theme has to do with CPT code "families." (A "family" in CPT parlance is a group of related codes, like 83890-83912 in molecular diagnostics or all the Pap test codes in the cytopathology section of the book.) Medicare and others look for situations in which the technical code's family doesn't match that of the professional code, whether the disparity involves an independent lab's global service claim or two claims, one each from a hospital and a pathologist. Typically, somebody's

[1] *Two exceptions are noted: Codes 88141 and 88291 for physician interpretation of an abnormal Pap test and of a conventional or molecular cytogenetics study respectively aren't payable to a hospital via the OPPS fee schedule. However, there are technical-only codes—for example, 88142 and 88271-88275—that a hospital should bill to get paid for its facility services in these two situations.*

charge(s) or a code or two is denied in this situation. Frequently seen invalid configurations include:

- The NCCI table says you can't report molecular diagnostics test interpretation code 83912 with a probe-based microbiology technical code like 87520. If you interpret such a test, report a clinical consult code for the service (80500 or 80502).
- Another forbidden matchup is an immunology total count code like 86064 (B cells) or 86359 (T cells) with a flow cytometry interpretation code (88187-88189). In the unusual event that a pathologist's interpretation of such a test is medically indicated, the professional fee should be reported with a clinical consult code (80500 or 80502): The lab shouldn't switch to the flow cytometry technical codes (88184-88185) in this situation.
- Medicare's clinical lab test fee schedule doesn't cover the professional component of the service. So when an independent lab's pathologist interprets a "presumptive list" test like serum protein electrophoresis (84165) or serum immunofixation (86334), it has to bill both the unmodified code and the 26-modified professional code to receive full payment (for example, 84165 plus 8416526); sometimes separate claims are required, depending on the carrier or private insurer. To view all Medicare "presumptive list" tests, go to section 60E in chapter 12 of the *Medicare Claims Processing Manual* (CMS IOM Pub. 100-4) on the CMS Web site at *www.cms.hhs.gov*. (You have to mentally add new—for 2005—codes 84166 and 86335 to the list, because CMS hasn't gotten around to it yet.)
- Routine and high-risk screening Pap test services must be billed to Medicare with HCPCS Level II codes, not CPT codes: Only "diagnostic" Pap tests, as defined by the program and determined by the patient's attending physician, can be billed with a CPT code. If a screening Pap test turns out to be abnormal and is interpreted by a pathologist, both the pathologist and the lab should report a HCPCS Level II code to Medicare: The pathologist shouldn't report CPT code 88141. Mixing CPT and HCPCS Level II codes typically results in one charge being denied, even when two entities bill them separately.

Don't Use HCPCS Level II Codes With Non-Medicare

The universe of HCPCS Level II codes used by pathologists and histology/cytology labs is very small: There's G0364 (report with 38221 when a pathologist performs concurrent bone marrow aspiration and biopsy procedures through the same wound); G0124, G0141, and P3001 (for a pathologist's exam of a routine or high-risk screening Pap smear thought by the cytotechnologist to be abnormal); and G0123, G0143-G0145, G0147-G0148, and P3000 (lab reporting of a routine or high-risk screening Pap test).

The HCPCS Level II codes for labs and pathologists fundamentally apply only to Medicare accounts. (Once in awhile you'll run across a Medicaid agency or private insurer who uses these codes.) When you report such a code for a non-Medicare patient, the insurer doesn't know what to do with the charge, so it's denied. Hence, don't report a HCPCS Level II code to payers other than Medicare, unless you know for certain that the payer or insurer wants those codes used.

The savvy reader will notice the omission of 16 histology/cytology HCPCS Level II codes from the enumerated "universe." The "dental (oral) pathology" codes D0472-D0502 describe basic tissue and cytology specimen exams, consultations on referred material, and add-on procedures, like special stains. Several are valid in Medicare's physician and OPPS fee schedules.

These D-codes at the moment pose a moral and ethical dilemma for hospitals billing the technical component of the service. That's because each pays something around $800 per unit instead of $25-$35 for their CPT counterpart, according to the 2005 OPPS APC table. To make a long story short, CMS officials advise that no one—not a pathologist, an oral pathologist, a hospital, or an independent lab—should actually report one of these D-codes to a carrier or fiscal intermediary:

You're supposed to use the applicable CPT code, even for a true "oral" biopsy or other specimen.

The problem is there's no regulation or program manual instruction that backs up the advice of the very knowledgeable CMS officials. (In-depth research suggests CMS most likely never intended the D-codes to be payable, but nobody ever got around to making that designation in the claim processing instructions.) Before you bill a D-code to your Medicare intermediary, get the OK from your compliance officer and hospital attorney. Pathologists and independent labs should ignore these codes altogether, due to the "carrier priced" feature attached to them in the physician fee schedule.

Document Need For Flow And IHC On Same Case

Notwithstanding the fact that combination flow cytometry phenotyping/immunohistochemistry (IHC) studies on some lower GI and other biopsies are commonly ordered today, Medicare, via the NCCI, says you can't bill codes 88184-88189 and 88342 together for the "same or similar specimen" in most instances. Flow cytometry is considered the "comprehensive" code in this instance, so 88342 is denied if done on the same day. NCCI asserts that flow and IHC are "duplicate" tests under most circumstances, because the diagnosis can allegedly "be established using [just] one of these methods."

This edit isn't binding on all combination flow/IHC situations. Separate procedure modifier 59 may be used to override the edit in three instances:

1. The two special studies are used on significantly different specimens (e.g., flow on breast and IHC on colon). NCCI defines "similar" specimens as "blood and bone marrow; bone marrow aspiration and bone marrow biopsy; two separate lymph nodes; or lymph node and other tissue with lymphoid infiltrate."
2. One method is nondiagnostic or doesn't explain all the light microscopy findings.
3. The abnormal cells in two or more specimens studied via flow and IHC are morphologically dissimilar.

The pathologist responsible for the case is in the best position to determine if an exception to NCCI's flow/IHC bundling edit applies in a given situation. This is particularly true if one method can be said to not completely explain the H&E findings; for example, the results of the studies might be complementary, but neither one by itself is entirely definitive. Some suggest this edit isn't as onerous as it appears at first glance due precisely to the leeway offered by the concept of complementary vs. duplicative tests and results.

Flow cytometry and IHC studies are expensive and time-consuming: No one can afford to give away willy-nilly too many of the latter to Medicare or anyone else. Therefore, it behooves pathologists to exercise good faith and prudent judgment case-by-case to determine whether a flow/IHC bundling edit exception applies. The pathologist must then fully and clearly describe the exception in his or her medical report, and the agreed upon mechanism by which the billing office is notified to append modifier 59 to the 88342 code must be activated. Coders shouldn't report the 59 modifier unless the pathologist says to do so.

Render Unto Caesar (Medicare)

For four short years, 1992-1995, the AMA's decades-long crusade to have just one set of physician procedure charge coding rules at play in this country was attained! Then along came the NCCI, and the concept of "universal" coding has become increasingly contorted ever since. We're now back to two sets of coding rules: Medicare's and everybody else's.

It's a mistake in judgment to apply Medicare's rules to payers and insurers who haven't formally jumped on the NCCI bandwagon. This is true for physicians, hospitals, and independent labs alike. You're encouraged to adopt the "render unto Caesar" approach to medical service coding to avoid unnecessarily conservative financial performance: If it's a Medicare account, follow the NCCI rules; otherwise, adhere to the AMA's instructions. A "Medicare account" for these purposes includes Medicaid agencies, managed care companies, and private insurers who've expressly incorporated NCCI into their physician payment formulary. Following the "render unto Caesar" philosophy means, by way of a few examples:

- You bill non-Medicare for every abnormal peripheral blood smear that's reviewed and reported by a pathologist (85060), not just inpatient smears as Medicare prescribes;
- Non-Medicare accounts are billed the flow cytometry phenotyping and IHC studies on one specimen, provided both are medically indicated (*see discussion at left*);
- Direct smears (88104) and concentrated smears (88108 or 88112) on one non-gynecological cytology specimen are separately reported for non-Medicare patients, even though Medicare bundles the former with the latter;

- A touch preparation (88161) on a non-Medicare patient specimen is reported separate from the frozen section (88331) or H&E section (e.g., 88305) on the same specimen, despite the NCCI bundling edits to the contrary; and
- Zero to 3+ scoring of immunohistochemistry is a semi-quantitative result, so code 88360 or 88361 (manual vs. computer assisted, respectively) is reported for non-Medicare accounts, even though NCCI claims 88342 (qualitative result) is appropriate in this situation.[2]

And for Your Further Enjoyment…

Three matters deserve at least brief attention in the context of minimizing charge denials and compliance risk. They're too important to overlook altogether, but a detailed explanation can be gained elsewhere. The subjects in mind are as follows:

- **Synoptic Reporting.** So-called "synoptic" reporting is the coming thing in pathology it seems. It's more a method of organizing and presenting a pathologist's diagnostic findings than anything else, but it often represents a very significant change from the process-oriented reports you're used to. Synoptic reporting is promoted as an enhancement from a medical communication perspective, but it can destroy your ability to effectively convey to coders and regulators information that's needed to determine and defend your chargeable services per case. This dramatic deficiency can be overcome relatively easily, but your conscious attention is needed to make it happen. For additional information on this topic, see the July 2003 synoptic reporting article, the June 2004 cancer protocol article, and Padget's September 2004 letter to the editor, all in *CAP Today*.
- **Hospital TC Billing for Anatomic Outreach Work.** A speaker during the April 21, 2005, Washington G-2 Reports audio conference on hospital outreach financial management explained that many hospitals are throwing away more than half the Medicare payment they're legally entitled to for the technical component of physician office biopsies by not correctly billing the charge. The work is supposed to be billed on Form CMS-1500 to the Medicare carrier using a Part B provider number; instead, hospitals mistakenly file a UB-92 claim with the fiscal intermediary, using their regular Part A provider number. For an in-depth description of this problem and step-by-step solution, refer to the article "Outreach Patient Tissue Biopsy: How To Help Your Hospital Avoid Losing Medicare dollars" in the September 2004 issue of *CAP Today*.
- **Important New Use for Old Code 86586.** From 1993, when it was first introduced, through 2004, "unlisted antigen" CPT code 86586 was intended as part of the "skin test" family (e.g., Candida, tuberculosis). Starting with *CPT-2005*, the code is standalone, and the AMA says it's the appropriate item to report for all "not otherwise specified" markers in flow cytometry panels for immunological disorders. For example, report 86586 three times for the HLA-DR, CD28, and CD38 markers in an immune dysfunction panel that also includes a CD3 (86359), CD4/CD8 (86360), and CD19 (86064) marker.

The problem is code 86586 isn't in Medicare's clinical lab test fee schedule; it appears only in the OPPS fee schedule, still as part of the "skin test" family, with a payment rate that's only slightly more than a tenth that of the "specified" immunology total count codes. That basically means independent labs can't get paid for the code today. Hopefully this mess will be straightened out in the 2006 Medicare clinical lab test fee schedule via CMS's July 18, 2005, open-door forum. Meantime, independent labs and hospitals billing for outreach work should use unlisted immunology test code 86849.

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[2] *Refer to the Errata on page 20 of the February 2005 issue of CAP Today for confirmation that 0 to 3+ scoring is semi-quantitative. Also be aware that some pathologists and labs contend that NCCI doesn't have to be followed in this instance, because the premise of the rule is unequivocally, demonstrably false. Consult an attorney before you knowingly depart from the NCCI.*

Lab Billing Settlement, *from p. 1*

Medicare claims for outpatient and nonpatient laboratory services from Jan. 1, 1991, through Dec. 31, 1999, violated the False Claims Act.

The hospital was charged with overbilling Medicare by unbundling and/or duplicating charges for blood chemistry tests and certain urinalysis services, including hematology services, double billing for platelet counts and hematology profiles, and unbundling two hematology procedure codes.

The same billing problems were discovered by Pennsylvania officials in a Medicaid audit and were called to the hospital's attention in 1993. This should have alerted the hospital to the likelihood of similar findings in its Medicare billings for outpatient laboratory services, the government alleged. However, the hospital did not disclose that possibility to Medicare authorities, take corrective action, or refund any overpayments to Medicare, according to the complaint.

Restitution Sought

The government sought $1 million in restitution for alleged overpayments, treble damages, civil penalties, pre- and post-judgment interest, and costs.

In addition to the $4.2 million payment, terms of the settlement require Abington Memorial Hospital to enter into a corporate integrity agreement with the Health and Human Services Office of Inspector General (OIG) and to take certain additional compliance measures for five years.

Those measures include hiring a new compliance staff independent of the hospital's internal audit staff and an independent review organization; developing and implementing a program to audit hospital and physician billing and coding, billing system integrity, and patient refunds; and expanding pre-bill editing capabilities.

In addition, the hospital is required to implement an education program dealing with corporate integrity and compliance, billing, coding, and collections for all staff members, and to implement a corporate refund policy under which overpayments will be investigated and resolved with all payers within 90 days.

"The monetary settlement is significant, but perhaps equally as important are the steps that have been taken to ensure that the conduct in question doesn't repeat itself," U.S. Attorney for the Eastern District of Pennsylvania Patrick Meehan said in a statement. "The new compliance staff will conduct audits annually or more often if deemed necessary to make sure the hospital is operating within the framework of the agreement."

Resources

- Settlement agreement: *www.usdoj.gov/usao/pae/News/Pr/2005/may/Settlement.Final.pdf*
- Corporate integrity agreement: *www.usdoj.gov/usao/pae/News/Pr/2005/may/Settlement.CIA.Final.pdf*

Senate Approves Crawford As FDA Chief

The Senate late July 18 confirmed Lester Crawford to serve as commissioner of the Food and Drug Administration (FDA).

The vote came after Sens. Hillary Rodham Clinton (D-N.Y.) and Patty Murray (D-Wash.) agreed to withdraw the hold they had placed on Crawford's nomination over the FDA's lack of action on Barr Pharmaceuticals Inc.'s application to sell emergency contraceptives over the counter. The senators released the hold after FDA agreed to issue its long-awaited decision on so-called Plan B contraceptives by September 1.

At the same time, Sen. Tom Coburn (R-Okla.) agreed to release his hold on the nomination, after receiving assurances from officials that condom labels would comply with a law that they be made medically accurate by warning against certain sexually transmitted diseases.

Health Plan Pays $1.6 Million In FCA Settlement

By the end of 2005, AmeriChoice must implement a plan that allows each participating physician to view on the AmeriChoice provider Web site, on a confidential basis, the complete, detailed fee schedule that applies to that physician.

AmeriChoice of Pennsylvania Inc. (Philadelphia) will pay the federal government $1.6 million and enter into a corporate integrity agreement to resolve allegations relating to claims processing and coverage determinations from 1995 through 1998, the U.S. attorney's office for the Eastern District of Pennsylvania announced June 30.

The civil settlement also calls for a first-of-its-kind claims processing system that gives providers information needed to ensure timely processing and payment for appropriate claims submissions.

The government alleged that from September 1995 through June 1998, AmeriChoice violated the False Claims Act by failing to process or pay providers' health claims in a timely fashion or at all and inaccurately reporting claims processing data to Pennsylvania regulators.

The alleged reporting violations included failure to meet self-reporting requirements and to impose self-assessment penalties as required under the company's Medicaid managed care contract with the state. The government also alleged False Claims Act violations in connection with AmeriChoice's coverage and failure to cover home health services to qualified beneficiaries.

The company denies any wrongdoing, but agreed to the settlement to avoid the uncertainty and cost of litigation, according to the agreement.

"Healthcare providers depend on timely payment by insurers," U.S. Attorney Patrick Meehan said in a statement. "The bottom line is that if the system isn't working properly and the provider isn't getting paid, it is ultimately the patient who suffers."

Noting that AmeriChoice took significant and costly steps to improve its claims system, Meehan expressed the hope that other managed care companies will follow its lead and "if necessary, revamp their claims processing systems to ensure timely and appropriate reimbursement to healthcare providers."

Meehan said the AmeriChoice settlement agreement and corporate integrity agreement provide a model for managed care companies to ensure compliance with the payment requirements of the state of Pennsylvania and the federal government.

AmeriChoice agreed to maintain an automated query system that will allow participating providers to determine, without charge, detailed information on the status of all claims submitted within the last 120 days along with the reason why any claims were denied.

Resource

❖ U.S. Attorney's Office, Eastern District of Pennsylvania: 215-861-8200

CMS Proposes Criteria For Anti-Fraud Contracts

The Centers for Medicare & Medicaid Services (CMS) has proposed criteria for use in selecting private contractors to perform specific anti-fraud and abuse functions under the Medicare Integrity Program (MIP). Among the functions are utilization and claims reviews, cost reports and audits, recovery of overpayments, Medicare secondary payer review, and provider education.

The rule defines types of entities eligible to become MIP contractors, outlines the process for awarding contracts, and clarifies that new Medicare Administrative Contractors (MACs) may perform MIP functions under certain circumstances.

Currently, CMS contracts with fiscal intermediaries to process Part A claims and with carriers to process Part B claims. Historically, about one-quarter of Part A and Part B contractor budgets has gone toward program integrity efforts.

Effective Oct. 1, 2005, CMS has the authority, under the 2003 Medicare Modernization Act, to begin replacing current intermediary and carrier contracts with competitively awarded MAC contracts. The transition is to be completed in 2011. The MACs will handle many of the basic functions now assigned to intermediaries and carriers and also may be assigned specific program integrity duties.

WellPoint To Pay $198 Million To Settle Docs' Lawsuit

Wellpoint Inc. (Indianapolis) will pay as much as $198 million to settle a national class action brought by physicians, alleging that it and other managed care companies violated federal racketeering and state prompt-pay laws in processing claims.

In separate statements, 28.5-million-member WellPoint and attorneys representing some 700,000 plaintiff physicians said the proposed settlement calls for WellPoint to establish a $135 million physician compensation fund. In addition, the company is to contribute $5 million to a foundation to promote increased quality and enhanced delivery of care to disadvantaged and underserved patients. WellPoint also will pay $58 million in the physicians' legal fees.

Archie Lamb, an attorney in Alabama and co-lead counsel for the plaintiffs, said the agreement also requires WellPoint to implement business-practices changes that will reduce physicians' overhead costs, as well as time spent contesting claims. Together, the payments and changes will be worth about $250 million, Lamb said.

The agreement, which must be approved by U.S. District Judge Federico Moreno of the Southern District of Florida, makes WellPoint the fifth managed care provider to settle the long-running lawsuit. In May, Health Net Inc. and Prudential Financial Inc. struck similar deals with the physicians.

In its settlement, Health Net agreed to pay at least $60 million as well as to invest some $80 million in business-practice changes. Prudential Financial Inc., which operated Prudential Health Care until it was acquired by Aetna Inc. in 1999, agreed to pay $22.2 million. In 2003, Aetna and CIGNA HealthCare Plan reached $470 million and $550 million settlements, respectively, with the physicians.

For the Record

New Lab Test Codes For 2006

The Centers for Medicare & Medicaid Services (CMS) held a public forum July 18 to get input on how fees should be established for new CPT lab codes on the 2006 Medicare Part B lab fee schedule. The following is a list of the CPT coding changes developed by the American Medical Association's CPT Editorial Panel. New codes are in bold; the final digit has yet to be finalized.

CHEMISTRY

• 82270 (*revised*)	Blood, occult, by peroxidase activity (eg, guaiac), qualitative, feces; consecutive collected specimens with single determination, for colorectal neoplasm screening (i.e., patient was provided three cards or single triple card for consecutive collection)
• **8227x**	single specimen, (e.g., from digital rectal exam)
• 83036 (*revised*)	Hemoglobin; glycosylated (A1C)
• **8303x**	glycosylated (A1C) by device cleared by FDA for home use
• **8363x**	Lactoferrin, fecal; quantitative
• **8369x**	Lipoprotein (a)
• **8370x**	Lipoprotein, blood; electrophoretic separation and quantitation
• **8370x**	high resolution fractionation and quantitation of lipoproteins including subclasses when performed (eg, electrophoresis, ultracentrifugation)
• **8370x**	quantification of lipoprotein particle numbers and lipoprotein particle subclasses (eg, by nuclear magnetic resonance spectroscopy)
• 83898 (*revised*)	Molecular diagnostics; amplification of patient nucleic acid, each nucleic acid sequence
• **8390x**	amplification of patient nucleic acid, multiplex, first two nucleic acid sequences each
• 83901 (*revised*)	amplification of patient nucleic acid, multiplex, each additional nucleic acid sequence (List separately in addition to code for primary procedure)
• **8390x**	lysis of cells prior to nucleic acid extraction (eg, stool specimens, paraffin embedded tissue)
• **8390x**	signal amplification of patient nucleic acid, each nucleic acid sequence
• **8390x**	separation and identification by high resolution technique (eg, capillary electrophoresis
• **8391x**	Mutation identification by enzymatic ligation or primer extension, single segment, each segment (eg, oligonucleotide ligation assay (OLA), single base chain extension (SBCE), or allele-specific primer extension (ASPE)) (Note: codes 83715 – 83716 deleted)

IMMUNOLOGY

• **8620x**	Cyclic citrullinated peptide (CCP), antibody
• **8635x**	B cells, total count
• **8635x**	Natural killer (NK) cells, total count
• **8636x**	Stem cells (i.e., CD34), total count
• **8648x**	Tuberculosis test, cell mediated immunity measurement of gamma interferon antigen response (Note: codes 86064, 86379, 86587 deleted)

MICROBIOLOGY

• **8720x**	Smear, primary source with interpretation; complex special stain (eg, trichome, iron hemotoxylin) for ova and parasites
• **8720x**	Infectious agent drug susceptibility phenotype prediction using regularly updated genotypic bioinformatics

HIPAA Complaints: The Centers for Medicare & Medicaid Services (CMS) is proposing a new system of records for intake and management of complaints alleging violation of certain rules issued under the administrative simplification provisions of the Health Insurance Portability & Accountability Act (HIPAA). According to a notice published in the July 6 *Federal Register*, "The purpose of this system is to store the results of all OESS (Office of E-Health Standards and Services) regional investigations to determine if there were violations as charged in the original complaints, to investigate complaints that appear to be in violation of the Transactions and Code Sets, Security, and Unique Identifier provisions of HIPAA, to refer violations to law enforcement activities as necessary, and to maintain and retrieve records of the results of the complaint investigations."

Medicare Appeals: Effective July 1, the Department of Health and Human Services (HHS) is handling Medicare claims appeals, a function previously conducted by the Social Security Administration. The Office of Medicare Hearings and Appeals will handle fee-for-service Medicare claims appeals brought by beneficiaries. In a July 1 statement, HHS said it was committed to improving the appeals process by hearing appeals faster and making it easier for beneficiaries to participate in the process closer to home. Among the ways the department plans to reduce hearing times is by using video teleconferencing to conduct electronic hearings in more than 1,000 cities nationwide in conjunction with traditional in-person hearings.

Merck Lawsuit: Texas Attorney General Greg Abbott on June 30 sued Merck & Co. for alleged Medicaid fraud, saying the company was "pushing to place the prescription painkiller Vioxx on the state's Medicaid formulary while knowing that it caused a higher risk of heart attack and cardiovascular problems." The Texas Medicaid program reimbursed pharmacists $56 million for Vioxx prescriptions they filled for patients over a five-year period, according to Abbott, who is invoking a provision in state law that allows for that amount to be tripled to $168 million.

Tenet Names Compliance Officer: Tenet Healthcare Corp. has named Steven Ortquist as its new senior vice president for ethics and compliance and chief compliance officer. The announcement comes amid ongoing legal battles Tenet is facing in California and Florida. Ortquist is leaving Banner Health as that hospital company's vice president for ethics and compliance/chief compliance officer. His new position is effective August 1.

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