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New 2005 Lab Test Codes Unveiled, Pricing Input Sought

After this first round of public comment on fees for new lab test codes in 2005, CMS will hold a second and final round on its proposed determinations. It will then finalize its decisions in the 2005 fee schedule, expected to be published this October

In advance of the July 26 public forum for receiving input on how fees should be set for new CPT lab codes to be added to the Part B lab fee schedule, the Centers for Medicare & Medicaid Services has just released a list of these codes. The coding additions, developed by the American Medical Association's CPT Editorial Panel, include six in chemistry, four in immunology, and one in microbiology (*see p. 2*).

CMS also published a list of new CPT codes for which it wants recommendations regarding their placement on the lab fee schedule and, if so, at what payment levels. Of special interest to pathologists, the list includes five new flow cytometry codes and three new morphometric analysis codes.

The July 26 forum is intended, CMS says, to provide expert input on the nature of the new test codes and to receive recommendations on establishing fees for them using either the cross-walk or the gap-fill method.

➥ *p. 2*

INSIDE *NIR*

Rapid Oral-Fluid HIV Test Gets CLIA Waiver

The Food & Drug Administration has approved a CLIA waiver for the rapid oral-fluid HIV test made by OraSure Technologies Inc. (Bethlehem, PA), but has attached restrictions on its use similar to those imposed on the company's waived rapid HIV blood test. The OraQuick ADVANCE Rapid HIV-1/2 Antibody Test may be sold only to clinical laboratories with adequate quality assurance programs and may be used only by an agent of the lab and only if test subjects are given a related information booklet. Further, its use is limited to detection of antibodies to HIV-1, and it is not approved for blood donor screening.

Test subjects collect the oral fluid sample by swabbing their gums. The sample is then placed in a vial, with results in about 20 minutes. If HIV antibodies are present, reddish purple lines appear in a small window on the device. The test looks for antibodies in crevicular fluid, which is essentially plasma leaching from capillaries of the gums, FDA's Elliot Cowan tells the *National Intelligence Report*. Positive results require confirmatory testing. FDA granted market clearance to the OraSure test last Mar. 26 and urged the manufacturer to apply for waived status, saying wider use would encourage more screening and greatly reduce risk to health workers since they won't be exposed to blood (*NIR, 25, 12/Apr. 5, '04, p. 8*).

CMS has two methods for setting fees for new lab codes. When a code is cross-walked, it is linked to an existing, substantially equivalent code and that code's established fee. When a code is gap-filled, the fee is based on local pricing patterns of Medicare carriers

New 2005 Lab Codes, *from p. 1*

Below are the newly created CPT lab codes for which CMS will consider pricing recommendations for the 2005 lab fee schedule. The last digit of each code has yet to be finalized:

Chemistry

8204x Albumin; ischemia modified
8265x Elastase, pancreatic (EL-1), fecal, qual. or semiquant.
8300x Helicobacter pylori; blood test analysis for urease activity, non-radioactive isotope (*eg*, C-13)
8363x Lactoferrin, fecal, qual.
8416x Pregnancy-associated plasma protein-A (PAPP-A)
8416x Protein, electrophoretic fractionation and quantitation; other fluids with concentration (*eg*, urine, CSF)

Immunology

8606x B cells, total count
8633x Immunofixation electrophoresis; other fluids with concentration (*eg*, urine, CSF)
8637x Natural Killer (NK) cells, total count
8658x Stem cells (*i.e.*, CD34), total count

Microbiology

8780x Infectious agent antigen detection by immunoassay with direct optical observation; respiratory syncytial virus

Cytopathology

8818x Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; first marker
8818x each additional marker (list separately in addition to code for first marker)
8818x Flow cytometry, interpretation; 2-8 markers
8818x 9-15 markers
8818x 16 or more markers

Surgical Pathology

8836x Morphometric analysis, tumor immunohistochemistry (*eg*, Her-2/neu, estrogen receptor/progesterone receptor), quant. or semiquant., each antibody; manual
8836x Morphometric analysis, in situ hybridization (quant. or semiquant.), each probe; using computer-assisted technology
8836x manual

CPT codes © American Medical Assn.

Medicare Extends Deadline For Lab Competitive Bids

Citing the need for more time, the Centers for Medicare & Medicaid Services has extended, to July 26, the due date for proposals to design and implement a Medicare competitive bidding demonstration for independent laboratory services. The demo is one of several bidding pilots required by last year's Medicare Modernization Act.

The Medicare reform law requires the HHS Secretary to pursue a Part B lab bidding demo but sets no deadline other than Dec. 31, 2005 for a progress report. Pap smears and colorectal cancer screening are excluded from the demo, which targets lab tests provided without a face-to-face encounter between the individual and the hospital personnel or physician performing the test

CMS had initially set June 4 as the due date for lab competitive bids from its 14 R&D master task order contractors. That date was moved to July 26 after prospective bidders requested more time, the CMS project officer, Linda Lebovic, tells *NIR*. These bidders are drawn from a pool of contractors that qualify to compete for R&D task orders over a five-year period. After receiving the bids, CMS will begin the review process, which typically takes four to six weeks.

Not Necessarily Going Dutch

In 1997, CMS and the Research Triangle Institute (Research Triangle Park, NC) drafted a Dutch-auction type of lab bidding process. That process, which CMS later adapted for use in a bidding pilot for durable medical equipment, has become popular in other contexts—for example, high-tech ventures like Google have begun using it to boost revenue from their initial public offerings. In the version RTI proposed, CMS would weight test-specific bids by anticipated test volume to form composite bids, which it would array from lowest to highest. CMS would establish a new fee schedule based on the average of the winning bids, while excluding the losing bidders. Under this approach, labs have a strong incentive to bid low to make sure they get in as winners.

Note: Linda Lebovic will speak about the lab competitive bidding demo at Lab Institute 2004, sponsored by Washington G-2 Reports on Sept. 29-Oct. 2 at the Crystal Gateway Marriott in Arlington, VA.

Lebovic tells *NIR* that CMS has not made any decision about using a Dutch auction or taking any other type of approach with the upcoming lab demo. "We are totally open on the design. There aren't any leanings one way or the other."

Managed Care Reform Reignites As Election Campaign Issue

On the same day the high court ruled, Rep. John Dingell (D-MI) introduced a Patients' Rights bill that he says is identical to one passed by the Senate in 2001, but it's likely to be bottled up in committee as the GOP and the Democrats take the issue to the voters

No sooner had the U.S. Supreme Court ruled unanimously that HMOs can't be sued in state court than Democrats pounced on the Bush Administration and the congressional GOP leadership for stalling action on a Patients' Bill of Rights. Democrats argue that internal HMO appeal panels for handling disputes are inadequate and enrollees who have been harmed when their health plan denies medical care need state courts to redress grievances.

In a June 21 ruling, the court held that the 1974 federal law governing benefits and pensions (ERISA) preempts state right-to-sue laws. The decision affects some 130 million Americans who get managed care coverage through private employer and labor union plans; it also voids right-to-sue laws in at least 10 states, including California and Texas. HMO enrollees still can sue in federal court, but awards are limited to minimum amounts.

The presumptive Democratic presidential nominee, Sen. John Kerry (MA), criticized the President for not backing "the same legislation he used to brag about in Texas." Kerry was referring to a right-to-sue bill that Bush, as governor, let become law without his signature, then praised during the 2000 presidential campaign. The right to sue has been a stumbling block to a federal Patients' Bill of Rights. The GOP says it would trigger frivolous lawsuits that would drain HMO coffers and cause hikes in premiums and other out-of-pocket costs.

focus on: Physician Self-Referrals

Controversy Flares Over In-Office Ancillary Services

The final Phase II regulations under the Stark II statute were published as an interim final rule with a comment period, so further modifications may be in store. The agency also notes that it will address, in a future rulemaking, how Stark II applies to Medicaid services

On the 26th of this month, final Phase II rules implementing the federal ban on physician self-referrals (Stark II) take effect for laboratories and other affected healthcare providers. The rules were published by the Centers for Medicare & Medicaid Services earlier this year (*NIR, 25, 12/Apr. 5, '04, p. 1*).

But already, the Stark exception for in-office ancillary services, including laboratory testing, has come under fire. The American Clinical Laboratory Association wants CMS to tighten the requirements. The aim is to thwart proliferation of business arrangements that tap pathology referrals to boost specialty physicians' revenue. And recently the HHS Office of Inspector General signaled its concern that these arrangements could also violate federal anti-kickback law *(NIR, 25, 17/June 21, '04, p. 1)*.

ACLA Takes Aim At "Pod" Labs

The in-office exception protects referrals by a physician to his or her own practice for laboratory and other designated health services provided through the practice. The services must be furnished in the same building where the referring physician provides medical services or, in the case of a group practice, in a central building. The physician or group must own or lease the space on a continuous, exclusive basis (shared lab sites are not permitted). And the services must be supervised by the physician, those in the group or a physician hired as an independent contractor. These criteria aim to ensure that the services are truly ancillary to the core medical practice and are not a separate business enterprise.

ACLA says it's alarmed over "the growing phenomenon" of business arrangements between physicians (mainly urologists, dermatologists and gastroenterologists) and pathologists to whom the physicians refer specimens. According to ACLA, these deals involve either joint venture arrangements (dubbed "Pod" labs) or situations where a lab performs anatomic pathology work and bills the ordering physician who then marks it up and passes it on to Medicare: "These arrangements encourage overutilization, may increase the number of specimens biopsied and potentially adversely affect the quality of patient care."

A typical Pod arrangement involves a facility manager who sets up turnkey labs for 10 to 15 large specialty group practices in adjacent offices (each leased to a different group). The labs share a histologist, who provides technical services, and a pathologist, who interprets and supervises the testing. The pathologist usually does the work under contract with the group, and the manager usually hires the

The Stark Statute At A Glance

The Stark law, named after its chief congressional proponent, U.S. Rep. Pete Stark (D-CA), bans referrals by physicians to healthcare facilities with which they (or an immediate family member) have a financial relationship, by investment interests or compensation arrangements, or both.

The intent is to prevent overutilization of services and abusive billing of Medicare and Medicaid. The law contains numerous exceptions, and new ones have been added by regulatory action.

The original ban—Stark I, enacted in 1989—applied only to laboratory services reimbursed by Medicare. In 1993 and 1994, the ban was expanded to 10 other designated services and to Medicaid referrals (Stark II).

Stark I final rules took effect in 1995. Stark II rules were finalized in two parts: Phase I, effective Jan. 4, 2002, and Phase II, effective July 26, 2004.

Scope Of Stark II/Phase II Rules

The Stark II/Phase II final rules address the following business arrangements and include responses to comments that CMS received on its previous Phase I rulemaking:

— General exceptions for ownership or investment in publicly traded securities.

— Additional exceptions pertinent only to ownership or investment interests: physician ownership of whole hospitals, rural providers and hospitals in Puerto Rico.

— Exceptions related to compensation arrangements include: physician services, rental of space or equipment, bona fide employment relationships, personal service and management arrangements, physician recruitment, payments that physicians make for certain items/services, isolated transactions, and remuneration unrelated to the provision of designated health services.

Phase II also changes reporting requirements. Instead of reporting on a periodic basis about their financial ties with physicians, entities furnishing services subject to the Stark law must make this information available at the government's request.

histotech. The group pays the pathologist a set fee per slide and pays the manager a management fee to cover lease costs and salaries. The group then bills for the entire pathology service, including both professional and technical components.

ACLA says the group's limited role in the "Pod" lab shows that the services are not truly "ancillary." The association further argues that the growth of such arrangements has been "inadvertently fueled" by two main CMS drivers: first, a change in the Phase I rules that allowed independent contractor physicians, such as pathologists, to supervise in-office ancillary services even though these physicians have minimal contact with the group; second, the agency's interpretation of exceptions to the ban on benefits reassignment, approved under the Medicare Modernization Act of 2003 (*NIR, 25, 11/Mar. 22, '04, p. 1*).

As a remedy, ACLA wants CMS to, among other things:

- ❑ Clarify that entities must meet the applicable requirements of the self-referral law even if they qualify for the new contractual arrangement exception to the general ban on reassignment of benefits.
- ❑ Define more clearly what is considered a "centralized building" to prevent the space from being subdivided into "Pod" labs. ACLA also favors requiring that use of the space be on a full-time basis and be "commercially reasonable." Further, ACLA wants CMS to consider requiring that the centralized building be within a certain radius of the group practice offices. Certain "Pods" are located at a great distance from the groups they serve and sometimes are not even in the same city or state.
- ❑ Clarify the term "physician in the group" to specify that a pathologist who is hired by the physician practice to supervise technical staff cannot furnish billable services in a centralized building unless the pathologist is a member of the practice.

Curbs Eased On Recruiting Physicians

In another area of potential fraud and abuse—even as federal prosecutors go after a California hospital and its former CEO for allegedly "bribing" physicians with relocation packages (*NIR, 25, 17/June 21, '04, p. 1*)—the Phase II final rules relax restrictions on recruiting physicians. For example, they allow hospitals to offer revenue guarantees and rent subsidies. Also, to qualify for the Stark physician recruitment exception, hospitals previously could only recruit doctors from other service areas. Now, they may recruit residents and physicians who have been practicing medicine for less than one year in their own service areas.

In comments filed with CMS, the American Hospital Association urges the agency to:

- ❑ Delete a Stark provision that prevents physicians or group practices from imposing restrictions, such as non-compete agreements, on recruits. AHA says such restrictions are standard in many areas.
- ❑ Permit use of pro-rated allocation when establishing income guarantees.
- ❑ Let hospitals recruit in outreach areas.

For an in-depth discussion of the Stark and kickback risks associated business deals involving pathologists and specialty physicians, join our Aug. 5 audioconference, "Pathologists in the Crosshairs: Legal Spotlight on Specialty Labs Run by Non-Pathology Medical Practices," 2-3:30 p.m. (Eastern). To register, call 1-800-401-5937 or visit our Website, www.g2reports.com

Other Stark Changes

- ***Fair market value:*** Most Stark exceptions require that payments be set at "fair market value," based on a commercially reasonable valuation method that does not take into account the volume or value of referrals. In the Phase II final rules, CMS describes two methods which it deems appropriate for determining hourly compensation for a physician's personal services: use emergency room rates for your area or the 50th percentile of various CMS-specified physician compensation surveys.
- ***Leasing arrangements:*** The rules address a concern by laboratories that lease space mainly or exclusively to draw blood or to test specimens from the physician practice leasing the space. Labs worried that these arrangements might not be considered "commercially reasonable even if no referrals were made between the parties." CMS has clarified that the term "referrals" means referrals for designated health services covered under Medicare only. Thus, if an arrangement makes commercial sense based on the physician's or group's non-Medicare referrals, plus testing for patients of other physicians (including Medicare patients), the "commercially reasonable" standard would be met.
- ***Professional courtesy:*** Entities may extend free or discounted services to a physician or a physician's immediate family member or office staff, if various conditions are met. But labs should be wary, healthcare attorneys advise, because the OIG, in a 1994 Fraud Alert directed at labs, described professional courtesy as an inducement that could implicate the federal anti-kickback statute.
- ***"Get Out of Jail Free":*** A new exception is created for certain arrangements that inadvertently fall out of compliance for reasons beyond the control of the entity providing services subject to the Stark ban. This is what attorney S. Craig Holden, COO for Ober/Kaler (Baltimore, MD) calls the "get out of jail free" card. This card, which allows non-compliance to continue for as long as 90 days before sanctions can be imposed, may be played only once every three years. The 90-day period starts when non-compliance begins, but AHA thinks it should start when the non-compliance is discovered.

Overall Assessment

Attorney Peter Kazon with Mintz Levin (Washington, DC) thinks that CMS has made a good effort to reduce the Stark regulatory burden and to clarify areas of previous confusion. But the size and complexity of the rules makes this difficult in all instances. "The line may be bright in some places, but it's still pretty fuzzy in others."

Robert Mazer, a partner with the law firm of Ober/Kaler (Baltimore, MD) agrees that the agency has shown flexibility in minimizing the impact of the Stark law on many common business arrangements. But at the same time, he observes, the agency has significantly raised the stakes for all healthcare providers, especially in light of severe sanctions for violating the ban. For years, providers have sought regulatory guidance on Stark compliance; now, that guidance is essentially complete. So, labs and other affected providers will find it much harder to defend questionable practices.

Specialty Hospital Moratorium

Interested in how the government is interpreting the 18-month moratorium imposed by Congress on construction of new specialty hospitals? You can get a sample of its reasoning in a recent Stark advisory opinion (AO-SH-2004-06-01, at *cms.hhs.gov*).

The moratorium, which took effect last Dec. 8 and runs to June 8, 2005, applies to specialty hospitals furnishing cardiac or orthopedic care and surgical procedures. It "grandfathers" specialty hospitals under development or in operation as of Nov. 18, 2003 (*NIR, 25, 12/Apr. 5, '04, p. 7*).

In the advisory opinion, CMS considered whether the hospital, a joint venture between orthopedic surgeons and neurosurgeons, met the "under development" standard. The agency analyzed the architectural plans, the funding received, requisite zoning requirements and necessary approvals from state agencies, then concluded that the hospital satisfied the standard and could proceed with construction.

Educators, Lab Officials Target Staffing Challenges

The staffing crisis has been building as cuts in funding have decimated lab personnel training programs nationwide, the number of students in the pipeline is on the decline, and the lab workforce gets older and closer to retirement—more than 72% are over age 40

Staffing problems posed by the nationwide shortage of clinical laboratory personnel were addressed last month at a conference in Washington, DC, sponsored by the American Association for Clinical Chemistry, the American Society for Clinical Laboratory Science and the American Society for Clinical Pathology. On the "to-do" list were changes proposed for the classroom and the workplace. One problem is automation, which, clinical lab educators and employers acknowledge, has created a disconnect between an individual's training and the work he or she eventually does. This is exacerbated by job dissatisfaction over relatively low pay.

One hurdle for students is the rigorous, wide-ranging laboratory science curriculum, said Craig Lehmann, PhD, dean of the School of Health Technology Management at the State University of New York in Stony Brook. Many who take it have no intention of working in labs, but see the training as a steppingstone to other careers, such as physician assistants. Lehmann, who supports a narrower curriculum focus, said today's wide-ranging approach "is a wonderful curriculum to get someplace other than clinical lab sciences."

Joeline Davidson, administrative director for laboratory services at West Georgia Medical System in LaGrange, said one way to make the work more compelling is to get laboratorians more involved in the patient care setting. Just as some hospitals now have a pharmacist on every floor, so too they could have a laboratorian on every floor.

Jim Fantus, CEO of SED Laboratories in Albuquerque, NM, emphasized creating a worker-friendly environment. Worker training is key, he noted—it cut turnover of phlebotomists at SED to 5% from 30-40%. Fantus said the fact that there are people who study lab science to prepare for another profession "is a selling point to get people into the program. Then you lobby them to stay in it."

♦CODING A·D·V·I·S·O·R·Y

Also as of this Oct. 1, Medicare will no longer grant a 90-day grace period to make the transition to the updated ICD-9 codes. Grace periods for both ICD-9 and CPT updates have been eliminated by a HIPAA requirement that applies to all code sets

Your laboratory has until Oct. 1 of this year to adopt the latest update to the ICD-9 diagnosis coding system. Part B claims lacking a valid ICD-9 code will be returned as "unprocessable," warns the Centers for Medicare & Medicaid Services. The update contains some significant coding changes for diagnostic Pap smears, notes Joan Logue, head of Health System Concepts in Longwood, FL. Codes for these procedures, as well as anatomic pathology, are the only ICD-9s assigned by labs; all others that relate to lab testing are assigned by the ordering physician.

The changes include four new Pap smear codes:

- ❑ 795.03 ..... Pap smear of cervix with low grade squamous intraepithelial lesion.
- ❑ 795.04 ..... Pap smear of cervix with high grade squamous intraepithelial lesion.
- ❑ 795.05 ..... Cervical high risk human papillomavirus (HPV) DNA test positive.
- ❑ 795.08 ..... Unsatisfactory smear, inadequate sample.

The ICD-9 update also makes several changes to codes covered under the lab National Coverage Decisions for blood glucose and HIV testing, and adds new codes for West Nile virus and hepatitis C. The CMS contact for more information is April Billingsley, *abillingsley@cms.hhs.gov*, 410-786-0140. Also check out *cms.hhs.gov/manuals/pm_trans/R211CP.pdf*.

Division Of Lab Systems To Move Up At CDC

As part of a planned reorganization, the Division of Laboratory Systems (DLS) is being relocated to a new, higher-profile unit within the Centers for Disease Control & Prevention in Atlanta, GA, an agency official tells *NIR*. On Oct. 1 of this year, the DLS will be moved to a new Coordinating Center for Health Information & Service, says Toby Merlin, MD, associate director of DLS for laboratory medicine. The division currently is housed in the Public Health Practice Program Office, which is being disbanded.

The lab unit handles CDC's CLIA responsibilities, provides staff support for CLIAC, plays a lead role in cytology PT, monitors lab practices, runs the Model Performance Evaluation Program for new tests and co-sponsors the National Laboratory Training Network

Along with the lab division, the Coordinating Center will include the National Center for Health Statistics (Hyattsville, MD), a new center for health informatics and a center for marketing. "We regard this as very good news," Merlin notes, "because this Center is going to be the major interface between CDC and its customers." At the helm will be James Marks, MD, MPH, current head of CDC's National Center for Chronic Disease Prevention & Health Promotion, which will be subsumed into another coordinating center.

CDC announced its reorganization strategy last April. The shakeup is part of the agency's Futures Initiative to focus more attention on preventing risks, while maintaining efforts to control the spread of infectious diseases (*NIR, 25, 14/ May 10, '04, p. 3*). CDC is grouping its many units into "coordinating centers" to reduce the number reporting to agency director Julie Gerberding, MD, MPH.

G-2 Audioconference Alert

Discover how lab medicine expert teams, working in conjunction with providers within healthcare organizations, can improve disease management outcomes and reduce medical errors.

Join us on **Wednesday, July 21**, 2-3:30 p.m. (Eastern), to discuss this cutting-edge topic with featured speaker Eleanor Travers, MD, MHA. Continuing education credit is available.

Register now for the audioconference, *"Introducing Lab Interdisciplinary Teams to Reduce Medical Errors: Justifying the Need for Clinical Privileges for Lab Professionals."* G-2 subscribers: $227; non-subscribers, $277.

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