WASHINGTON G–2 REPORTS

NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 27th Year of Publication

Vol. 27, No. 16, June 12, 2006

House Bills Part Ways Over Proposed Switch To ICD-10 Codes

The ICD-10 issue is part of broader legislation to promote the adoption of health IT and e-health records, including expanded anti-kickback and Stark safe harbors that allow providers to furnish health IT resources to referral sources.

A provision mandating replacement of the current ICD-9 diagnosis and procedure coding system with ICD-10 by 2009 was dropped from the health information technology bill (H.R. 4157) that the House Energy & Commerce health subcommittee approved June 8.

However, the controversial proposed switch to ICD-10—opposed by a host of insurer, medical, and laboratory groups, including the American Clinical Laboratory Association—is contained in the version of H.R. 4157 that originated in and passed the House Ways & Means health subcommittee May 24.

Having no legislative requirement for the transition is ACLA's preference, president Alan Mertz told the *National Intelligence Report*. But if it survives in a final House bill, ACLA says the deadline should be no sooner than 2012. Markup of H.R. 4157 by the full Energy & Commerce Committee is scheduled for the week of June 12. The Ways & Means Committee has yet to set a date to markup its version of the legislation. For more on this sensitive issue, see the *Focus*, pp. 4-5.

INSIDE *NIR*

How Should Medicare Price New 2007 Lab Codes?

That's the question up for discussion at a July 17 public meeting that the Centers for Medicare & Medicaid Services will hold to get input from clinical laboratory and pathology organizations and other interested parties on how to establish fees for CPT lab codes to be added to the Part B lab fee schedule for 2007. The forum will run from 10 a.m. to 3 p.m. (Eastern). To listen in, dial 410-786-3100, CMS says, and at the prompt, use conference ID #178976.

Lab fees are set using either the gap-fill or crosswalk method. Crosswalking is used to match a new test code to a similar existing code and pay at that code's rate. Gap-filling is used when there is no comparable existing test. In this case, local carriers set the fee for the first year, based on local pricing patterns; CMS then taps these amounts to establish a fee cap for following years.

The new lab codes will be posted on or after June 19 at *www.cms.hhs.gov/ClinicalLabFeeSched*, CMS said in a May 26 *Federal Register* notice. A summary of the codes, payment recommendations, and CMS's tentative fee decisions will be posted at the same address by September 8. CMS will accept more comments through September 22 and unveil its final fee decisions later this year in Medicare's 2007 lab fee schedule.

Medicare Begins Online Disclosure Of Hospital Pricing Data

Due up next on the Internet, according to CMS officials: later this summer, payment data for common elective procedures in ambulatory surgery centers; coming in the fall, payment data for common hospital outpatient and physician services.

In line with the Bush Administration's priority to make healthcare cost and quality data more transparent to consumers, the Medicare program on June 1 began to post on the Internet how much it pays for 30 elective inpatient hospital procedures, along with other data on hospital admissions. The move fulfills the President's pledge last month to make such information available on the Web (*NIR, 27, 15/May 22 '06, p. 6*).

The Administration wants the private sector to follow suit. Health & Human Services Secretary Michael Leavitt noted: "The federal government is the biggest single purchaser of healthcare in America, and by taking steps to post prices and quality data, we encourage more insurance companies, hospitals, clinics, and doctors to do the same." The premise behind price transparency is that empowering consumers as "smart shoppers" will promote competition among providers, leading to lower healthcare costs.

The CMS online posting shows the range of Medicare payments by county for 30 diagnosis-related groups (DRGs) and the number of cases treated at individual hospitals in fiscal 2005. The DRGs include heart operations and implanting cardiac defibrillators; hip and knee replacements; kidney and urinary tract operations; gall bladder operations; back and neck operations; and common non-surgical admissions. Also posted were several files with pricing and other data aggregated at county, state, and national levels, including one file of the top 30 elective inpatient hospital DRGs and another file of highly utilized DRGs of special interest to Medicare. The data are posted at *www.cms.hhs.gov/HealthCareConInit/01_Overview.asp#TopOfPage*.

CMS said it is working closely with a number of national and local organizations to develop more comprehensive and personalized information on healthcare quality and cost. For example, quality measures on hospitals across the country are currently reported to the public at *www.HospitalCompare.hhs.gov*, supported by the Hospital Quality Alliance. The measures address heart attack, heart failure, pneumonia, and surgical infections and clinical laboratory testing for specific conditions (*NIR, 26, 22/Sept 26 '05, p. 6*). In the coming year, CMS plans to expand the data to include patient satisfaction and outcomes.

House Chairman Wants More Disclosure

Just as CMS got the hospital pricing disclosure initiative underway, the head of the House Ways & Means Committee, Rep. Bill Thomas (R-CA), said he wants Medicare to do more. In a May 30 letter to CMS administrator Mark McClellan, MD, PhD, Thomas urged the agency to quickly adopt its proposed severity-adjusted DRG system for hospital payments and to expand requirements for hospital price reporting. He said hospitals should be required to report a range for all of their payments and an average self-pay (uninsured patient) amount for selected services, and urged CMS to work with the industry to develop definitions for reporting cost data.

Thomas reiterated his call for the HHS Office of Inspector General to "immediately" finalize its proposal, issued in 2003, to exclude providers who charge Medicare "substantially in excess" of their usual charge. Earlier this year, Thomas scolded Leavitt over the OIG's "failure to act," saying this hobbles the President's pricing transparency strategy (*NIR, 27, 11/Mar 27 '06, p. 3*). The OIG proposal defines "substantially in excess" as any amount above 120% of the usual charge. Critics throughout the clinical lab community say the proposal threatens discounts to physicians and could even force labs to accept less than Medicare pay rates to avoid program exclusion (*NIR, 24, 22/Sep 29 '03, p. 1*).

CMS To Phase-In, Limit 'Medically Unbelievable" Edits

MUEs are software controls that would limit the units of service for a particular CPT/HCPCS code that can be billed per Medicare beneficiary per day. Claims exceeding the limits would be automatically denied.

While committed to going forward with its "medically unbelievable" edits (MUEs), the Centers for Medicare & Medicaid Services will phase-in their implementation, beginning January 2007, and the initial MUE list will be much less restrictive than in the current proposal, according to a top agency official.

At a May 22 briefing of the Practicing Physicians Advisory Council, Lisa Zone, deputy director of CMS's Program Integrity Group, also said the unit-of-service limits during the initial phase-in would concentrate on anatomic anomalies and obvious typographical errors. CMS, she added, is seriously considering use of modifiers to bypass MUEs and development of an appeals process.

The current MUE proposal, released in mid-January, ignited strong protests from pathology and laboratory groups for its sweeping nature and for what they saw as arbitrary limits without regard to clinical practice guidelines and other standards of quality care. The proposal clamps unit-of-service limits on virtually all CPT/HCPCS codes, including clinical lab and pathology codes.

A shorter and revised MUE list will be released for public comment later this year, Zone said. Meantime, the comment period on the current proposal is open until June 19, and the College of American Pathologists and the American Society for Clinical Pathology are urging their members to submit comments to help CMS further refine the list.

And as they have since the MUE controversy flared in January, CAP, ASCP, and the American Clinical Laboratory Association keep pressing CMS to clarify the ground rules on important issues, including the rationale and method behind the proposed MUEs, modifiers to bypass MUEs when appropriate, avenues for appeals, and periodic review and revision of existing edits. At its recent meeting, PPAC joined this call, recommending to CMS that it provide guidance to providers on these issues (*see box*).

CMS reportedly plans more modifications to the MUE process. In a May 26 letter following up on a meeting the day before with Kimberly Brandt, director of CMS's Program Integrity Group, ACLA spelled out its understanding of the proposed revisions discussed and asked her to confirm several key points:

- ❑ Lab and pathology groups do not have to meet the June 19 comment deadline.
- ❑ No lab or pathology codes will be included in the January 2007 phase-in.
- ❑ CMS will establish a separate process and timeline for defining which lab or pathology codes should be subject to MUEs
- ❑ Any resulting list would not take effect until mid-to-late 2007.

ACLA further noted, "We agreed that the process would focus on truly abnormal situations, such as occur in other specialty areas, where a provider bills for anatomic impossibilities or clearly outrageous or egregious situations … we do not believe these are common in the clinical lab and pathology fields, but we are open to the discussion."

PPAC's MUE Recommendations

— CMS should remove the term "unbelievable." Some suggested replacements: "unlikely," "unusual," etc.

— CMS should allow modifiers for services that may be clinical outliers and develop an appeals process for claims denied under the MUE program.

— When CMS publishes its proposal for an MUE subset to be implemented in January 2007, it should provide information on the rationale for the edits and specific data on the estimated percentage of errors CMS hopes to address.

Approved May 22, 2006. Source: PPAC meeting transcript.

focus on: Healthcare Coding Issues

Controversy Flares Over Mandated Switch To ICD-10 Codes

The proposed 2009 start date for use of ICD-10 "would make implementation of HIPAA transaction standards look easy," said one lab industry source.

Though Medicare has required ICD-9 diagnosis coding on Part B lab claims for many years, many clinical laboratories still find it difficult to get these codes from test-ordering physicians—and without the codes to justify the medical necessity of the testing, Medicare won't reimburse the claims. Some labs even have staff whose sole job is to follow-up and get the codes from doctors' offices, so they can submit payable claims.

Now, the lab community faces the prospect that it could have to switch to the vastly different and more complex ICD-10 coding system by 2009. That depends for now on what House health leaders decide to do about differing versions of the Health Information Technology Promotion Act (H.R. 4157).

The version approved by the Ways & Means health subcommittee May 24 mandated the transition to ICD-10 for standard electronic transactions by October 1, 2009. But the version passed by the Energy & Commerce health subcommittee June 8 contains no such provision. (In the Senate, health IT legislation—S. 1952, introduced last November—also calls for moving to ICD-10 by 2009, but the bill is still pending before the Health, Education, Labor & Pensions Committee.)

The shift to ICD-10 entails going from 13,000 diagnosis codes and 11,000 procedure codes under ICD-9, in use in this country since 1979, to approximately 120,000 diagnosis codes and 87,000 procedure codes. Compounding the complexity of the changeover is the fact that ICD-9 data sets cannot be converted into ICD-10 data sets or vice versa, so the shift would require a major overhaul of coding and billing systems/software.

"While we wouldn't see a huge expansion of the number of codes that labs include on their claims submissions, what matters is the proposed change to a completely new set of codes—from 5-digit numeric codes to 7-digit alphanumeric codes," Jason DuBois, vice president of government relations for the American Clinical Laboratory Association, told *NIR*. "This will require retraining staff, updating computer systems, and educating physician and hospital clients." Based on labs' difficulties over the years in satisfying Medicare's ICD-9 requirements, the net effect is that labs would continue to write off a significant portion of money, he said.

ACLA is part of a coalition lobbying Congress on the proposed changeover to the ICD-10-CM and ICD-10-PCS coding and classification systems. The coalition—which includes America's Health Insurance Plans, the Blue Cross Blue Shield Association, the Medical Group Management Association, and the American College of Physicians, among others—argues that the pro-

Background On ICD-10

The International Classification of Diseases (ICD), version 10, was endorsed by the 43rd World Health Assembly in May 1990 and came into use in WHO member states beginning in 1994.

The ICD is the international standard diagnostic classification for all general epidemiological and many health management purposes. It is used to classify diseases and other health problems recorded on many types of health and vital records, including death certificates and hospital records.

In addition to enabling the storage and retrieval of diagnostic information for clinical and epidemiological purposes, these records provide the basis for compilation of national mortality and morbidity statistics by WHO member states.

Moving too quickly to replace ICD-9 would be especially burdensome, ACLA said, because labs already are inundated with a host of HIPAA standards, including electronic transaction updates, claims attachments, and national identifiers for providers and health plans.

posed implementation date of 2009 is too soon and more time is needed to accomplish it smoothly, with the fewest possible glitches.

ACLA prefers no legislative action on ICD-10, but if the transition remains in any final House bill, the deadline for implementation should be no sooner than 2012, association president Alan Mertz told *NIR*.

The ICD-10 transition is favored by the chair of the Ways & Means health subcommittee, Rep. Nancy Johnson (R-CT), who thinks it will help advance pay-for-performance initiatives by furnishing greater specificity on procedures and outcomes. She has strong support from the American Hospital Association, the Federation of American Hospitals, AdvaMed which represents medical device manufacturers, and the American Health Information Management Association. They say they are running out of procedure codes under the current system and are not getting accurately reimbursed. AHIMA has told the Ways & Means Committee that billing under ICD-10 would reduce fraud and improve Medicare payment accuracy because of the heightened level of specificity. "Up-to-date classification systems are essential," AHIMA insisted, "to the adoption of interoperable e-health records."

A big challenge in any switch to ICD-10, DuBois said, will be to get physicians to understand the new, much more highly specific coding system, and report the codes correctly. Without adequate physician compliance, labs can expect increased delays in submitting claims as well as more denial of claims, disrupting cash flow and requiring intensified follow-up. A hasty switch would be counterproductive to Johnson's intent, he added, because "providers would likely use the 'dump' codes for the ICD-10 codes in order to get paid, in lieu of using the most accurate code."

Moving too fast could make Medicare and other federal healthcare programs more vulnerable to fraud and abuse, warned the Blue Cross Blue Shield Association. This could undercut Medicare's success in trimming its payment error rate from 13.8% in 1996 to 5.2% in 2005, noted attorney D. McCarty Thornton, with Sonnenschein Nath & Rosenthal LLP (Washington, DC). He also suggested that ICD-10 be put off until after Medicare has consolidated its Part A and Part B claims processing functions in 15 new MACs (Medicare Administrative Contractors), expected to be completed in 2009.

Other Provisions Of H.R. 4157

In addition to the ICD-10 issue, H.R. 4157, as passed by both the Ways & Means and Energy & Commerce health subcommittees, would establish a clear federal role for the Department of Health & Human Services in encouraging private-sector efforts to expand the adoption of health IT and e-health records throughout the U.S. healthcare system.

The legislation also would expand safe harbors under federal anti-kickback and Stark physician referral prohibitions to allow providers such as hospitals and group practices to provide referral sources with HIT tools and training for the electronic creation, maintenance, and exchange of clinical health information.

It's important to note, ACLA chief Alan Mertz told *NIR*, that the version passed by the Energy & Commerce health panel makes it clear that labs would be included in these expanded safe harbors. Current safe harbor protection for labs is limited to test ordering and results reporting.

One big difference between the subcommittee versions concerns state privacy laws. The Ways & Means measure calls for a study of whether federal and state security and confidentiality laws can be made more consistent. If Congress does not act within 18 months after receiving the study, the HHS Secretary would have the authority to modify federal standards and preempt state laws in these areas. The Energy & Commerce measure is silent on the state preemption issue.

Legislation Would Expand, Promote Medicare Cancer Screening

U.S. Rep. E. Clay Shaw (R-FL) has recently introduced in the House two bills aimed at promoting and expanding Medicare-covered cancer screening services. The measures have been referred to the House Energy & Commerce and Ways & Means Committees.

One bill (H.R. 5514) would authorize Medicare to cover lung cancer screening tests for certain high-risk individuals as of January 1, 2007. The tests include a low-dose CAT scan, sputum analysis, fluorescent bronchoscopy, and "such other tests, and modifications to tests, as the HHS Secretary deems appropriate, in consultation with appropriate organizations." High-risk factors include a family history of lung cancer, a significant smoking history, exposure to certain toxic agents and carcinogens, and previous lung disease.

Another bill (H.R. 5437), also aimed at early detection, would extend the eligibility period for the baseline "Welcome to Medicare" physical exam for new beneficiaries from six months to one year, to give them more time to utilize the cancer screening to which they are entitled, including screening for breast, cervical, vaginal, colorectal, and prostate cancer. The legislation also would eliminate the 20% co-pay for a mammogram and for a colonoscopy.

In a separate screening-related development, the head of the Centers for Medicare & Medicaid Services, Mark McClellan, MD, PhD, has said that with the Part D drug benefit enrollment completed by May 15, the agency's focus will shift to making sure that beneficiaries take maximum advantage of the range of preventive services covered under Part B, including certain laboratory and pathology tests. Congress has greatly expanded Medicare coverage of screening benefits in recent years, but some studies show that only a small portion of beneficiaries get the screening. For example, CMS notes, the utilization rate for a Pap smear and pelvic exam was 36.3% in 2003.

Federal Response To Medical Disasters: Who Should Lead?

In more fallout from post-Hurricane Katrina criticism, key House committee leaders think the answer is the Department of Health & Human Services, not FEMA (the Federal Emergency Management Agency). Once independent, FEMA is now housed within the Department of Homeland Security.

Reps. Joe Barton (R-TX), chairman of the House Energy & Commerce Committee, and John Dingell (D-MI), the ranking minority member, are co-sponsors of legislation (H.R. 5438) that would make HHS responsible for coordinating the federal response to major medical emergencies, including bioterrorism. The bill was introduced May 22 and approved May 24 by the committee by voice vote.

FEMA now runs the National Disaster Medical System, but H.R. 5438 would shift that operation to HHS, including such functions as sending medical teams, supplies, and equipment to disaster areas and making sure patients in those areas are moved to safe zones. The bill would transfer these functions and related staff to HHS within nine months of enactment and would also move contracts and funding for the National Medical Emergency System to HHS.

Meantime, HHS also has the lead under the President's National Strategy for Pandemic Influenza in coordinating medical and public health preparedness and response. The plan assigns overall domestic incident management and federal coordination to Homeland Security (*NIR, 27, 4/Nov 28 '05, pp. 4-5*).

♦ MEDICARE CLAIMS & CODING A·D·V·I·S·O·R·Y

Providers Urged To Get New National ID Number

Clinical laboratories, pathologists, and other healthcare providers that haven't already obtained their National Provider Identifier (NPI) should do so sooner rather than later, says the Centers for Medicare & Medicaid Services, warning: "There's less than a year left, don't risk disruption to your cash flow!"

The NPI, established in accord with HIPAA (the Health Insurance Portability & Accountability Act), will be required on all Medicare electronic claims sent on and after May 23, 2007 (for small health plans, May 23, 2008). Medicare legacy numbers will no longer be accepted thereafter. Every healthcare provider should obtain an NPI, CMS says. The NPI is a 10-digit, numeric identifier that does not expire or change.

Three Ways To Get An NPI

1. Apply online at *https://NPPES.cms.hhs.gov*
2. Call the NPI Enumerator at 1-800-465-3203 to request a paper NPI application
3. Apply for a bulk enumeration to obtain a number of providers' NPI (for example, physicians in group practices or laboratories with multiple facilities)

Getting your NPI is just the first step in meeting the compliance deadline, the agency cautions: "Once you have your NPI, you may need to modify your business processes to accommodate [its] use. You will also need to share your NPI with other healthcare providers with whom you do business."

As part of the transition to the new provider ID system, CMS in January began accepting NPIs, along with Medicare legacy identifiers, from providers in HIPAA standard claims transactions.

New CPT Code Added To National Lipids Testing Policy

Effective July 1, 2006, CPT 83704, Quantitation of lipoprotein particle numbers and lipoprotein particles subclasses, will be added to the list of HCPCS/CPT codes covered under Medicare's national coverage policy for lipids testing. The change was announced by the Centers for Medicare & Medicaid Services in the latest quarterly update to the software module used to edit claims under Medicare's laboratory National Coverage Decisions, or NCDs (Change Request 5108, May 26, 2006).

The 23 lab NCDs were developed by a negotiated rulemaking committee and published as a final rule on November 23, 2001. Claims subject to the NCDs have been processed uniformly nationwide since January 1, 2003. The lab NCDs are online at *www.cms.hhs.gov/center/coverage.asp*. Go to Coverage Database and click on "lab NCDs only."

CLIAC To Hold Special Meeting On Cytology PT

Issues of special concern include annual vs. periodic PT testing, measuring proficiency at the lab level vs. individual testing, penalties, and the grading scheme.

The Clinical Laboratory Improvement Advisory Committee will convene a special meeting June 20-21 in Atlanta, GA, to discuss possible changes to the CLIA rules for gynecologic cytology PT and to consider recommendations from the workgroup it assigned to study this controversial issue. The meeting date and agenda were announced in the June 5 *Federal Register*.

The CLIAC session is a first step toward potential statutory and regulatory changes to the CLIA cytology PT requirements, written in 1992, to reflect changes in cytology science and practice since then (*NIR, 27, 8/Feb 6 '06, pp. 4-5*). The requirements have been sharply criticized by the College of American Pathologists and others since the Centers for Medicare & Medicaid Services began enforcing them nationwide in 2005, with only one approved PT provider. In a surprise vote last December, the House approved the suspension of CLIA cytology PT altogether until certain key changes are made. In January, CMS said it will hold off on cytology PT penalties this year and continue its educational approach to enforcement. For more information on the CLIAC meeting, contact Devery Howerton, acting chief, CDC's Laboratory Practice Standards Branch, 404-718-1016, e: *DHowerton@cdc.gov*.

 NATIONAL INTELLIGENCE REPORT (ISSN 0270-6768) is published twice monthly (except August and December, which are one-issue months) by Washington G-2 Reports, 3 Park Avenue, 30th Floor, New York, NY 10016-5902. Telephone: (212) 244-0360. Fax: (212) 564-0465. Web site: www.g2reports.com. Order Line: (212) 629-3679.

Jim Curren, Editor; Dennis Weissman, Executive Editor; Janice Prescott, Sr. Production Editor; Perry Patterson, Vice President and Group Publisher; Joe Bremner, President.

Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 212-244-0360, ext. 2.