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Medicare Sounds Alarm Over Rise In Physician Spending

With lab spending under Part B rising significantly in recent years, it's likely to attract greater scrutiny from policymakers, increasing the potential for new cost-saving controls that could cut deeper into lab revenue within the near-term future

Rapid growth in outlays for laboratory and diagnostic imaging services are partly to blame for the estimated 4.3% reduction in Medicare physician fees looming next year, said the Centers for Medicare & Medicaid Services in a March 31 letter to the Medicare Payment Advisory Commission (MedPAC).

Part B spending for physician services jumped by about 15% in 2004, according to the latest CMS data, with lab testing accounting for 11% of the growth and imaging 18%. Also contributing to the increase: spending for office visits (29%) and minor procedures (26%). "Understanding why Part B expenditures are rising so rapidly is of great concern," Herb Kuhn, director of the Center for Medicare Management, said in the letter.

The spending spike is factored into Medicare's sustainable growth rate, part of the formula used to adjust physician fees up or down. In 2006, the conversion factor for physician fees is set to drop to $36.2679 from $37.8975 this year. Many Washington insiders expect Congress to override a physician fee cut by mandating an increase, as it did for 2004 and 2005, guaranteeing at least a 1.5% hike for each of those years.

CMS To Increase Managed Care Fees

Health plans serving Medicare beneficiaries will get a 4.8% payment increase in 2006, the Centers for Medicare & Medicaid Services just announced. This is on top of a 6.6% increase they got this year (*National Intelligence Report, 25, 15/May 24, '04, p. 1*).

Medicare payments to plans traditionally were 95% of fee-for-service rates, but the Medicare Modernization Act raised the level to at least 100% and provided for even higher increases to get more plans to offer beneficiaries an option to fee-for-service under a new Medicare Advantage program. Under Medicare Advantage, clinical laboratories and other providers must negotiate prices with insurers, rather than get paid via Part B fee schedules.

From 1999 to 2003, many plans that signed up for Medicare+Choice—Congress's previous attempt to inject more managed care into Medicare—dropped more than two million beneficiaries, saying average annual increases of 2-3% weren't enough to cover costs. This year, Medicare Advantage plans, including HMOs and PPOs, should be up and running in 49 states, says CMS. The plans will get even more money for offering Medicare prescription drug coverage next year.

INSIDE NIR

Bills Target Shortages In Lab, Other Allied Health Personnel

Lab groups are telling Congress that according to estimates by the Bureau of Labor Statistics, clinical labs will need 12,000 additional qualified professionals annually until 2010, far more than the 4,200 graduating each year with associate or baccalaureate degrees in the field

Interest is growing inside Congress to beef up clinical laboratory education and training programs, say lab lobbyists, pointing to the introduction of several allied health bills with provisions to strengthen lab workforce development. The bills signal, according to lab groups, a greater awareness on Capitol Hill of the worsening shortage of trained personnel and the need for federal incentives to alleviate it.

Driving much of this interest is the pending reauthorization of Title VII of the Public Health Service Act, which includes allied health education/training programs. The latest five-year authorization expired September 30, 2003, though Congress has continued allied health funding levels despite the Bush Administration's repeated attempts to gut the funding (*NIR, 26, 9/Feb 21, '05, p. 5*). In fiscal 2005, Title VII health professions funds totaled $299.574 million. The President's budget seeks only $11 million for FY 2006 and no funding for health professions training activities.

Now, congressional leaders are expressing interest in proceeding with reauthorization legislation, which could be a vehicle for passing some of the lab-related provisions that members have proposed. "This is the year everyone's going to jump on the bandwagon," says Elissa Passiment, executive vice president of the American Society for Clinical Laboratory Science.

Lab Groups Back Three Legislative Initiatives

House bill 1175 is specific to lab workforce issues and is backed by ASCLS, the American Society for Clinical Pathology, and the Clinical Laboratory Management Association. It would authorize $11.2 million in new funding in fiscal 2006 for scholarship and loan repayment programs for medical technologists, medical lab technicians, and other lab personnel. The programs include a period of obligated service in a designated health professional shortage area or other area with a shortage of medical lab personnel. The legislation provides for funding awards for faculty development as well as public service announcements to promote careers in medical lab professions. Also, to increase the number of cytotechnologists trained to screen for cervical cancer, the bill would authorize $10 million in FY 2006, subject to certain limits.

In a record turnout on March 22, 130 members of ASCLS and CLMA participated in an annual visit to the Hill, where they, among other things, distributed a letter ASCP had drafted, encouraging House members to cosponsor H.R. 1175. They also urged senators to consider sponsoring a companion bill. Initial reports on the response were encouraging. Several senators were identified as possible sponsors, and the overall level of interest appeared to be much higher than last year. "For whatever reason," Passiment says, "it's sinking in this time around" that the growing gap between demand and supply will soon widen significantly as the aging lab workforce begins to retire.

Bills On The Table So Far

- *The Medical Laboratory Personnel Shortage Act of 2005* (H.R. 1175). Introduced March 8 by Rep. John Shimkus (R-IL), with three co-sponsors. Referred to the Energy & Commerce health subcommittee. The bill is identical to 2003 legislation, H.R. 623, which attracted 37 co-sponsors, but died in committee.
- *The Allied Health Professions Reinvestment Act of 2005* (H.R. 215). Introduced January 4 by Rep. Cliff Stearns (R-FL), with eight co-sponsors. Referred to the Energy & Commerce health subcommittee. The bill is identical to last year's H.R. 4016, which attracted 21 co-sponsors, but died in committee. The Senate companion measure is the *Allied Health Reinvestment Act* (S. 473), introduced February 28 by Sen. Maria Cantwell (D-WA), with two co-sponsors. Like last year's S. 2491, it was referred to the Health, Education, Labor & Pensions (HELP) Committee.
- *The Public Health Workforce Development Act of 2005* (S. 506). Introduced March 3 by Sen. Chuck Hagel (R-NE), with six co-sponsors. Referred to the HELP Committee.

Despite what happens with the bills and Title VII reauthorization, "the big challenge will be getting appropriations," says Jeff Jacobs, ASCP vice president for public policy

Lab groups also support broader legislation (H.R. 215 and S. 473), backed by the Association of Schools of Allied Health Professions. The bills would authorize scholarship and loan repayment programs across allied health professions, with a period of obligated service, along with faculty development funding and promotional campaigns for allied health careers. No authorized spending levels are set.

Finally, lab groups support a bill (S. 506) championed by the Association of Public Health Laboratories. Its focus is on scholarship and loan repayment programs to develop preparedness in the public health lab workforce to counter bioterrorism and outbreaks of infectious disease. For the scholarship program, $35 million would be authorized in FY 2006; for the loan repayment program, $195 million.

Florida Medicaid Cuts Independent Lab Fees

Reaction from ACLA president Alan Mertz was blunt: "We were already underpaid. Now we'll be even more underpaid"

Florida's Agency for Health Care Administration on April 1 imposed a 10% cut in Medicaid reimbursement for independent laboratory services, just as the state legislature had required unless the state had completed a winner-take-all procurement for these services. The state on February 18 withdrew an invitation to negotiate (ITN) a contract after the American Clinical Laboratory Association challenged it (*NIR, 26, 10/Mar 7, '05, p. 3*). Asked if AHCA intends to re-issue the procurement, spokesman Jonathan Burns told *NIR*, "The agency is reviewing its options, but hasn't made a final decision."

Lab interests have suggested the 10% cut may only remain in effect until the current fiscal year ends June 30, but Burns said the state intends to keep it in place indefinitely. The new fee schedule is at: *http://floridamedicaid.acs-inc.com/index.jsp?display=fees*.

"Compared to the competition for a single lab, the 10% cut is less of an evil to take," said Philip Chen, MD, PhD, president of Cognoscenti Health Institute in Orlando and leader of an informal alliance of some 25 independent Florida labs. But he told *NIR* it also potentially undercuts the state's most significant lab cost savings initiative. As part of the proposed procurement, the state was going to require the winning lab to interface with an electronic record system. This would help the state reduce costs by controlling utilization. And growing utilization is what has been driving Medicaid costs through the roof, he added. "It's very apparent from the Medicaid data that there is a tenfold difference in the utilization rate from one part of the state to another." If the state continues to pursue an electronic record system with a lab interface, the 10% cut makes it even tougher for labs to shoulder the upfront cost of tying into such an interface, he noted.

Meanwhile, the political challenges continue. In the Florida House, language was added to the appropriations bill on March 31 that would have allowed an end run around ACLA's challenge by authorizing AHCA to reissue its ITN without a formal rulemaking and without being subject to judicial review. The next day, under lab industry pressure, the appropriations committee removed the language. Amy Young of Smith Ballard & Logan (Tallahassee), who lobbies the state legislature for ACLA and the Florida Society of Pathologists, has been working to keep the 10% cut out of pending appropriations legislation, as well as anything like last year's ITN language. The Senate has added such language, while the House has not, so this issue will have to be resolved in conference. The 60-day legislative session does not end until May 6.

focus on: CLIA Quality Control

Search Is On For QC Options, Consensus On Standards

"Lab instruments are getting better and more stable all the time. So, do you need the frequency and expense of all this quality control?"— Glen Fine, executive VP, Clinical Laboratory & Standards Institute

Equivalent quality control continues to be the most controversial part of the final rule that revamped how clinical laboratories assess their testing quality in accord with CLIA (the Clinical Laboratory Improvement Amendments of 1988). But in a significant message at a recent "QC for the Future" meeting, a top CLIA official signaled that the government wants to work more in tandem with the lab professions and the private sector to balance federal quality oversight with technological changes in testing methods.

In a revised final rule for CLIA QC that took effect April 24, 2003, and in surveyor guidelines that came out some nine months later, the government established one set of quality standards for moderate and high complexity testing and reduced the frequency of QC testing for most specialties and subspecialties (*NIR, 25, 7/Jan 26, '04, p. 1*).

But it soon became apparent that equivalent QC was problematic. Speaking to a packed room at the "QC for the Future" meeting, Judy Yost, the top CLIA official at the Centers for Medicare & Medicaid Services, said, "There is innovative technology we did not anticipate, and we have created some policies that are not consistent with what the accrediting organizations have … I see this meeting as the first of many for people to collaborate using a consensus-like process."

Equivalent QC Policy

CLIA provides alternatives to the traditional testing of two levels of external QC materials each day a lab performs a non-waived test. For eligible test systems, an equivalent QC procedure may be used if it passes a QC evaluation process approved by CMS that demonstrates test system stability over time.

There are three equivalent QC options:

— If labs show 10 days of system stability, they can cut external control frequency to monthly for tests with internal controls for the entire analytic process.

— If labs show 30 days of system stability, they can cut external control frequency to once a week for tests with internal controls for part of the analytic process.

— If labs show 60 days of system stability, they can cut external control frequency to once a month for tests with no internal controls.

Whether or not the test procedure includes an extraction step, and the specialty/subspecialty of the test procedure, affects a test's eligibility for equivalent QC. Tests subject to specialty/subspecialty requirements for routine chemistry and hematology must have internal controls to be eligible. Not eligible are tests (including those with an extraction phase) that are subject to specialty/subspecialty rules *other than* routine chemistry and hematology.

Source: CLIA Equivalent QC Procedures, Brochure #4, *cms.hhs.gov/clia.*

The Clinical Laboratory & Standards Institute, which convened the March 18 meeting in Baltimore, MD, aims to play a key role in advancing such a consensus, said its executive vice president, Glen Fine. CLSI, formerly known as the National Committee for Clinical Laboratory Standards, is based in Wayne, PA. The Institute is active in efforts of the International Organization for Standardization (known by the acronym ISO, from the Greek for equal) to adapt risk management principles from the manufacturing sector to healthcare. CLSI publishes the General Practices 26 document on a workflow path for quality systems and is leading an initiative involving AdvaMed, the Centers for Disease Control & Prevention, and others to develop QC guidelines for test manufacturers. The "Principles of Manufacturers' Validation of Risk Mitigation Using Quality Control" (aka

When the manufacturer's instructions say do one thing, and CLIA says something else, who should you follow? The more stringent CLIA requirements, says Judy Yost, CMS's leading CLIA official: "If a deficiency is found, we must cite it"

Option 4) is on track to become a CLSI standard in 2006. The idea behind Option 4: if the Food & Drug Administration agrees that the validation shows the alternative to be equivalent to traditional QC, labs could follow it instead of the CLIA-mandated QC.

What About Using 'Six Sigma'?

CMS's equivalent QC process is not appropriate, its most well-known critic, Jim Westgard, PhD, FACB, told attendees. He is president of Westgard QC, Inc., and a professor in the pathology/lab medicine department at the University of Wisconsin in Madison. If anything, he said, CMS should increase the frequency of QC testing.

Westgard derived this conclusion from his analysis of the quality of cholesterol, glucose, and calcium testing as well as anti-coagulation monitoring and prostate-specific antigen screening in a sampling of 9,000 clinical labs' proficiency tests. He calculated a "critical systematic error" index to define "tolerance limits"—the size of error that QC procedures need to detect—based on the Six Sigma quality management methodology which, he said, is easy to apply to lab testing work.

"You have to start by defining what quality is needed," Westgard said, "then build a system around it. Then you can talk about quality control."

Is Risk Management The Answer?

Donald Powers, PhD, president of Powers Consulting Services (Pittsford, NY), suggested that labs take an approach to quality based on the ISO 14971 risk management standard for medical devices. This standard involves identifying all possible hazards, analyzing and evaluating the risk posed by each, establishing control measures, and monitoring results. For each risk, you calculate the likelihood of occurrence, the risk of harm, and the severity of harm. To control risks, you map the testing process, perform hazard analysis on the process steps where failures occur, then assign and verify essential control points.

The "QC for the Future" meeting is the latest in a growing swath of public sessions on CLIA quality. In February the Clinical Laboratory Improvement Advisory Committee mulled whether QC for microbiology should be changed. CLIAC is expected to continue its look into equivalent QC at a meeting this fall

"The ISO 14971 process *can* apply to labs … as a way to justify reduced quality control," Powers said, but added that more work needs to be done to judge the severity of harm that could result from lab errors. He suggested CLSI could do this via consensus error grids, similar to those the diabetes community uses.

The Human Factor

Elissa Passiment, EdM, CLS (NCA), executive vice president of the American Society for Clinical Laboratory Science, cautioned attendees about the human element. Regardless of what safety systems you include, "people can override anything at anytime. In every setting, what I have seen is that people will do what they believe to be correct, based on their experience and training. They will circumvent a system if they believe they know better." So, there's a major need, she pointed out, to train the growing ranks of non-specialists who perform point-of-care testing.

Valerie Ng, MD, PhD, shared a "from the trenches" perspective on point-of-care at San Francisco General Hospital. The lab she directs oversees that testing. "My personal belief is that quality must be inherent in the POC test. My experience is that the unexpected will occur, so you can't anticipate the risks." Ng recommended that all unitized devices should have step-by-step procedures printed in the cartridge, instruments should lock out personnel with the wrong ID or who don't enter patient information, and, if test results must be read within a specified time that has expired, the results should self-destruct.

CMS To Relax Certain Hospital Conditions Of Participation

The intent of the changes, says the agency, is to reflect current medical practice standards, give hospitals and practitioners more flexibility in patient care, and reduce unnecessary regulatory burdens

More than seven years after first proposing revisions to requirements in the hospital conditions of participation (CoPs), Medicare is once again revisiting the issue. In a rule issued March 24, the Centers for Medicare & Medicaid Services is proposing changes in the four areas noted below.

CMS first proposed extensive revisions to the entire set of CoPs on December 19, 1997. But internal delays prompted CMS to "carve out" specific CoPs as separate final rules, including organ, tissue, and eye procurement; patients' rights; anesthesia services-CRNA supervision; fire safety; and quality assessment performance improvement. Rather than simply go final with the latest carve-out, CMS re-proposed the revisions below "out of an abundance of caution" to comply with the Medicare Modernization Act which mandates that proposed rules be finalized within three years, except under exceptional circumstances.

Areas For Change

1 ***History & Physical Exam:*** CMS would expand the number of practitioners who may perform these and the time frame for their completion. Currently, only a doctor of medicine or osteopathy (or, for patients admitted only for oromaxillofacial surgery, an oromaxillofacial surgeon who has been granted such privileges by the medical staff in accordance with state law) may perform the history and physical exam. CMS would allow any physician, or other qualified individual granted these privileges by the medical staff in accordance with state law, to do the history and exam. Also, the time frame for completion, which now runs from seven days before admission to 48 hours after, would be changed to 30 days before and 24 hours after.

2 ***Verbal Orders:*** Currently, all orders, including verbal ones, must be dated, timed, and authenticated by the prescribing practitioner. CMS proposes that during a five-year transition from publication of the final rule, it would also allow all orders to be dated, timed, and authenticated by another practitioner responsible for care of the patient. The agency expects that a five-year period is sufficient for hospitals to adopt changes in information technology to make it easy for prescribing practitioners to authenticate all of their own orders in a timely fashion. Also, the proposed rule states that in the absence of a state law specifying the time frame to authenticate verbal orders, these orders would need to be authenticated within 48 hours. Finally, CMS clarifies current rules on who may accept verbal orders, authentication of all orders for drugs and biologicals, and authentication of medical record entries.

3 ***Medications:*** CMS would require that all drugs and biologicals be kept in secure areas, or locked when appropriate, to prevent unauthorized access. This addresses community concerns, provides flexibility for hospitals in determining control of non-scheduled drugs and biologicals, and is more patient-focused and outcome-oriented than the current requirement, the agency says.

4 ***Post-Anesthesia Evaluation:*** CMS would allow this evaluation of inpatients to be completed and documented by any individual qualified to administer anesthesia. The current CoP requires that the individual who administers the anesthesia do this evaluation.

The deadline for comments is May 24. The proposed rule is online at *http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/pdf/05-5916.pdf*.

Medicare To Speed Up Claims Appeals

Starting May 1, Medicare is implementing a major overhaul of the process that beneficiaries—and in certain circumstances, providers and suppliers—can use to appeal claims denial. Two laws mandated the restructuring: the Benefits Improvement & Protection Act of 2000 and the Medicare Modernization Act of 2003.

The time frame for handling fee-for-service appeals will be cut sharply—the process that now can exceed 1,000 days will be trimmed to 300. This, said the Centers for Medicare & Medicaid Services, has required a substantial revamping of all levels of the Medicare appeals process. The changes begin May 1, 2005, for Part A and January 1, 2006 for Part B, which involves the bulk of Medicare appeals. CMS said it expects the changes will reduce appellants' concerns over the fairness and timeliness of Medicare appeal decisions, leading eventually to a reduction in later-stage appeals.

The overhaul establishes uniform appeal procedures for both Part A and Part B claims, forces quicker decisions on appeals, establishes Qualified Independent Contractors (QICs) to reconsider claims denials by Medicare contractors, uses QIC review panels that include medical professionals to handle all reconsiderations involving medical necessity, and requires appeals-specific data collection by CMS.

In addition, the administrative law judge (ALJ) function will be transferred from the Social Security Administration to the Department of Health & Human Services no earlier than July 1, but not later than October 1 of this year.

♦CODING A·D·V·I·S·O·R·Y

Now that ICD-9 diagnosis codes are required on your Medicare claims, your lab will want to get updated ICD-9 guidelines, effective April 1. Items to note:

- ❑ The entire patient's record should be reviewed to determine the specific reason for an encounter and the conditions treated. The term "encounter" is used for all settings, including hospital admissions. The term "provider" means "physician or any qualified health practitioner who is legally accountable for establishing a patient's diagnosis."
- ❑ A V code related to genetic testing has been added. The code, V84-Genetic susceptibility status, indicates a person has a gene that increases his or her risk of developing a particular disease. The code may only be used as an additional code, not a principal/first listed code.
- ❑ In a related change, for an encounter for prophylactic removal of breasts, ovaries, or another organ due to genetic susceptibility to cancer or a family history of cancer, the principal or first listed code should be from subcategory V50.4, Prophylactic organ removal, followed by the appropriate genetic susceptibility and/or family history codes.

The guidelines also address coding for HIV infection, septicemia and related conditions, additional cancer-related conditions, diabetes mellitus, stroke, hypertension, pregnancy, newborns, poisoning and toxic effects, and various other conditions.

See the guidelines at *http://www.cdc.gov/nchs/data/icd9/icdguide.pdf*.

Contractor Picked For National Provider ID System

Fox Systems, Inc., has been selected by the Centers for Medicare & Medicaid Services as the contractor to support operations of the new standard unique healthcare provider identification (NPI) system required under provisions of HIPAA (the Health Insurance Portability & Accountability Act), designed to facilitate electronic data exchange.

Fox Systems is a national leader in providing consulting services to county, state, and federal agencies. It will be supported in the NPI project by its subcontractor, Noridian Administrative Services of Fargo, ND.

As "enumerator" for the NPI project, Fox will process applications from providers and run a help desk. Assignment of NPIs is to begin later this year, said CMS.

The final rule establishing the national unique provider identifier goes into effect on May 23, but providers don't have to do anything at this time, CMS stresses. The agency will announce when the system for handling the assignment of NPIs is ready and when providers may start to apply for an identifier.

In addition to the final NPI rule that takes effect next month, CMS has adopted final HIPAA standards for electronic transactions and code sets, the employer identifier, and the privacy and security of protected health information.

G-2 SPECIAL AUDIO CONFERENCE

April Audioconferences

• **Last call for the April 12 session**, *New Era Ahead for Laboratory Accreditation*. Discover how oversight is changing following quality lapses that went undetected during inspections but came to light in whistleblower allegations. Find out which surveys will be unannounced, and what that means. Speakers: Judy Yost, top CLIA official at CMS; CAP's Jared Schwartz, MD; JCAHO's Margaret Peck, MS, MT(ASCP). Please use priority code G2ACEM1 when registering.

• **April 21:** *Getting a Grip on Lab Outreach Financial Management*. Get expert advice on key billing, collection, and financial management issues and strategies. Speakers: Tom Hirsch, president, Laboratory Billing Solutions; Dennis Padget, president, DLPadget Enterprises; Barry Portugal, president, Health Care Development Services. Please use priority code LIRINS1 when registering.

Each audioconference runs from 2:00-3:30 p.m. (Eastern).

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