WASHINGTON G–2 REPORTS

NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 28th Year of Publication

Vol. 28, No. 18, July 16, 2007

Public Forum Puts Lab Bidding Demo Back In Play

Join us on August 2 (2:00-3:30 p.m. Eastern) for our special audio conference, Competitive Bidding For Clinical Lab Services: Where's It Heading & What Can You Expect? *Alan Mertz, president, American Clinical Laboratory Association, and Peter Kazon, senior counsel with Alston & Bird, will present an update on the demo and discuss the implications for clinical labs. Details and registration online at www.g2reports.com.*

In the shadows for months inside the Centers for Medicare & Medicaid Services, the demonstration project for lab competitive bidding is back in the political spotlight now that the agency is holding a July 16 open-door forum on a draft bidder's package.

The purpose of the demo is to determine whether competitive bidding can be used to provide quality lab services at prices below current Medicare payment rates.

While the draft bidder's package contains more details on the demo's design and the bidding process, it does not specify the sites for the demo and when the first demo will begin—questions of critical concern to national and local labs that could be required to participate.

The forum is being held, CMS says, to give the public an opportunity to discuss the draft and other demo issues with officials of the CMS project and its contractor for the project, Research Triangle Institute (RTI) International. The draft is online at *www.cms.hhs.gov*. Click on "Medicare," then "Clinical Labs Center." *Continued on p. 2*

Physician Fee Cuts, 'Pod Lab' Curbs Proposed

Under Medicare's proposed 2008 physician fee schedule, doctors would experience a cut of 10% in payments for their services as of January 1 under the statutory fee update formula. For pathologists, the cut would be even more—12% when the negative update is combined with changes in work and practice expense relative value units (RVUs) for services. For independent labs, the combined impact would be a cut of 7%.

The Centers for Medicare & Medicaid Services also is proposing new curbs on "pod" or "condo" labs, calling many—including those furnishing anatomic pathology services—"little more than enterprises established for the self-referral of designated health services," contrary to the Stark ban.

The College of American Pathologists and the American Society for Clinical Pathology welcomed the anti-markup proposals for diagnostic testing, but want CMS to also tighten the Stark in-office ancillary service exception that certain physician specialty groups have relied on to increase revenue and profits from pathology referrals. For more on proposed changes in physician payment policy, see the *Focus*, pp. 4-6.

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Lab Bidding Demo, *from p. 1*

The demo is planned to run for three years in two Metropolitan Statistical Areas within a single state and will set competitively bid fees for tests paid under Medicare fee-for-service, except Pap smears, colorectal cancer screening tests, and new tests added to the lab fee schedule during the demo.

The demo includes independent lab services defined as those without a face-to-face encounter with the beneficiary. This excludes lab tests performed by physician office labs (POLs) and by hospitals for their patients. However, it does include independent lab testing and outreach and/or non-patient services provided by a hospital or a POL where the lab is functioning, in effect, as an independent lab.

Dial-In For Lab Bidding Forum

July 16 (2:30 - 4:30 p.m. Eastern daylight time)

To participate by phone in the forum:
dial: 1-800-837-1935 & Reference Conference ID 2359678. (Persons participating by phone do not need to RSVP.)

Note: TTY Communications Relay Services are available for the hearing impaired. For TTY services, dial 7-1-1 or 1-800-855-2880 and for Internet Relay services, go to *www.consumer.att.com/relay/which/index.html*. A Relay Communications Assistant will help.

The demonstration is mandated by section 302(b) of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003.

Members of the Clinical Laboratory Coalition remain united in opposition even to the concept of using competitive bidding to pay for lab services, saying it treats these services as a commodity rather than a complex medical service. The American Clinical Laboratory Association is among those lobbying Congress to step in and repeal the demo before CMS proceeds further.

Asked how the new momentum on the demo will impact the lobbying effort, ACLA president Alan Mertz told *NIR* that the draft bidder's package underscores the industry's arguments against the project. It is "one of the most complex procurements I have seen in decades around Washington," he said, noting that it requires labs to submit bids on over 1,100 tests without any hint of the bid submission timetable.

The very complexity and questionable viability of the project only reinforce the concerns that ACLA and others in the industry have been presenting to legislators and staff on Capitol Hill. In the bid to get the demo repealed, Mertz told *NIR*, "This package is another arrow in our quiver," adding that there is definite interest in Congress to address lab industry concerns about Medicare competitive bidding.

NPI Update: Major Deadlines Looming

August 1 is the new target release date the Centers for Medicare & Medicaid Services has set for National Provider Identifiers (NPIs) and other provider data from the National Plan & Provider Enumeration System (NPPES). The previous target date was June 28, but CMS extended it, saying providers needed more time to check the accuracy of their NPPES data.

July 16 is the deadline for providers to make any changes and have these reflected in the initial NPPES data file to be released August 1. The file will be downloadable from the Internet and in a query-only database (called the NPI Registry) that users can search by provider NPI or provider name. Changes submitted after July 16 will be reflected in planned monthly update files, also downloadable from the Internet.

NPPES data are obtained from the application that providers submit to obtain an NPI. In a May 30 notice, CMS specified what data would and would not be

disclosed under terms of the Freedom of Information Act (*NIR, 28, 16/Jun 11 '07, pp. 4-6*). The agency specifically noted it will not disclose Social Security numbers, IRS individual taxpayer ID numbers, and date and country of birth.

Under a rule that took effect May 23 of this year, NPIs are required on Medicare claims, replacing all legacy provider numbers. However, Medicare has granted providers extra time, up to 12 months, to become compliant with NPI requirements as long as they can demonstrate a good-faith effort to do so. Meantime, as of June 29 of this year, CMS discontinued assigning Unique Physician Identification Numbers (UPINs) to Medicare providers. But the agency said it is considering extending access to the UPIN Registry until May 23, 2008.

More on National Provider Identifiers

- CMS NPI Web site: *www.cms.hhs.gov/NationalProvIdentStand/*
- Providers can apply for an NPI:
  - Online at the NPPES Web site, *https://nppes.cms.hhs.gov/* or
  - Call the NPI Enumerator for a paper application at 1-800-465-3203. The project enumerator is Fox Systems, Inc. (Scottsdale, AZ), under contract with CMS.
- Medicare fee-for-service contingency plan for NPI implementation (Change Request 5595, April 24, 2007): *www.cms.hhs.gov/transmittals*.

Pathology Measures Included For '08 Medicare Quality Reporting

Pathology measures will be included for the first time next year on the list of newly approved measures for Medicare's Physician Quality Reporting Initiative (PQRI), according to a proposal in the 2008 physician fee schedule, published in the July 12 *Federal Register*.

The quality measures for breast and colon cancer care are included on the PQRI list for 2008 currently under development by the AMA Physicians Consortium. The Consortium last month approved pay-for-performance measures for such care that the College of American Pathologists developed (*NIR, 28, 17/June 25 '07, p. 3*).

These and other new quality measures will be published in the final 2008 list, CMS says, provided they are endorsed by the National Quality Forum or adopted by the AQA (formerly the Ambulatory Care Quality Alliance) by November 15, 2007.

Lab measures new to the 2008 PQRI include GFR calculation, lipid testing, and hemoglobin monitoring in patients with chronic kidney disease, and hepatitis C genotyping and other monitoring of patients with hepatitis C virus infection.

The PQRI relies mainly on Consortium-endorsed measures, with about 80% of them developed by the group, including measures for treating hypertension, asthma, and heart failure. The Consortium was founded in 2000 to help create best care practices. Members include more than 100 national medical specialty and state medical societies as well as government and medical board members.

Meantime, the 2007 PQRI debuted July 1 and offers a bonus to eligible doctors who voluntarily report specified quality measures on Medicare fee-for-service claims. They may earn a bonus, subject to a cap, of 1.5% of total allowed charges for services covered under the Part B physician fee schedule.

The goal of the College of American Pathologists, which the AMA has selected to lead the PQRI pathology measures effort, is to get pathologists into the bonus payment pool, which CMS proposes to continue in 2008. CAP also is working on additional measures to be considered for PQRI approval for 2009.

focus on: Medicare Payment Policy

CMS Proposes Major Changes For Pathologists, Labs In 2008

Pathologists and independent clinical laboratories face a series of major changes in Medicare payment rates and coverage policy under the proposed physician fee schedule rule for calendar 2008.

The changes include steep Part B reimbursement cuts and elimination of the "grandfather" protection for qualified pathology technical component billings unless Congress intervenes.

Medicare also would impose new regulatory restrictions on controversial "pod" lab arrangements, a move backed by pathology and lab lobbies that argue that physician specialties use these labs to profit from pathology referrals by exploiting loopholes in benefits reassignment rules and Stark self-referral exceptions.

The Centers for Medicare & Medicaid Services published the proposed rule in the July 12 *Federal Register*, with a comment deadline of August 31. Under changes in the rule, CMS projects it will pay approximately $58.9 billion to 900,000 physicians and other healthcare professionals next year, or $5.9 billion less than this year.

In a July 2 statement, acting CMS administrator Leslie V. Norwalk, Esq., noted: "[It] builds on the changes CMS made last year to pay more appropriately for practice expenses and to [make] Medicare an active purchaser of higher quality services, rather than just paying for procedures. It also includes an important new initiative to encourage use of electronic prescribing to improve the speed and accuracy of care to beneficiaries, as well as proposals for additional quality measures for use in the Physician Quality Reporting Initiative in 2008" (*related PQRI story, p. 3*).

Cuts In Physician Fees

As CMS forecast in previous notices, a cut of 10% in Medicare physician fees is required, effective January 1, 2008, under the statutory SGR (Sustainable Growth Rate) formula used to calculate the annual update to the Part B fee schedule.

When the negative update is combined with changes proposed in the fee schedule's relative value units (RVUs) for work and practice expense, pathologists would feel even more of a cut—12%. For independent labs, the combined impact would be a cut

Combined CY 2008 total allowed charge impact for changes in work/PE RVUs & the CY 2008 Update

Specialty	*Allowed charges (mil)*	*Impact of work/PE RVU changes*	*CY 2008 Update*	*Combined impact with '08 Update*
Pathology	$939	-2%	-10%	-12%
Independent laboratory	$1,081	3%	-10%	-7%
Diagnostic testing facility	$1,162	0%	-10%	-10%

of 7%; for independent diagnostic facilities, a cut of 10%. The payment impact will vary by individual provider, based on volume and mix of services, CMS noted.

For the most frequently ordered pathology service, CPT 88305, the professional component (physician's interpretation) would decline from $37.90 to $32.77, a drop of 14%.

Democratic leaders of House health committees have said they aim to include a physician fee fix in an omnibus healthcare bill that would also be the vehicle for reauthorizing SCHIP (the State Children's Health Insurance Program) due to expire at the end of September. The goal is to move the bill through the House before the August recess.

According to a draft circulating at press time, the legislation would provide a physician fee update of at least 0.5% in 2008 and 2009 and replace the SGR with separate service expenditure targets. In the Senate, Finance committee chairman Max Baucus (D-MT) has pledged to prevent the 10% cut and is considering ways to replace the current SGR system. In its report to Congress earlier this year, the Medicare Payment Advisory Commission recommended a 1.7% physician fee increase in 2008 (*NIR, 28, 7/Jan 29 '07, p. 2*). Physician groups had been lobbying for an increase in line with MedPAC or at least a rise of 1.5% over the next few years until the SGR can be replaced. The SGR triggered a 5% reduction in the fee update in 2007, but Congress instead froze the update at zero.

Physician Self-Referral Prohibitions

In the proposed rule, CMS said it plans to "modify a number of physician self-referral provisions to close loopholes that have made the Medicare program vulnerable to abuse." The agency is proposing an anti-markup provision for the technical component (TC) and the professional component (PC) of diagnostic tests. It would apply whether "the billing physician or medical group purchases the PC or TC, or if the physician or other supplier performing the PC or TC reassigns their right to bill to the billing physician or medical group," according to the proposal.

Current Medicare rules prohibit markup of the TC of certain diagnostic tests performed by third-party suppliers and billed to Medicare by a different provider. The rules also restrict who may bill for the PC of such tests. CMS has expressed concern that the anti-markup and purchased interpretation requirements have led to confusion where reassignment of payment is made under a contractual arrangement. The agency also is concerned that certain arrangements that permit physician groups to bill for services provided by a contractor in a centralized building are inconsistent with the intended purpose of the Stark in-office ancillary services exception and may lead to program abuse and service overutilization. The proposed anti-markup provision is designed to address those concerns.

In addition:

- ❑ The PC of a purchased test would be subject to an anti-markup provision.
- ❑ The anti-markup provision for the TC and PC would apply to all arrangements not involving reassignment from a full-time employee of the billing entity.
- ❑ The performing physician's or other supplier's net charge would be calculated exclusive of any charge that reflects the cost of space or equipment leased to the performing physician or other supplier by the billing entity.
- ❑ The anti-markup provision would not apply to independent labs that have not ordered the TC.

CMS decided against proposing changes to the definition of "centralized building" under the in-office ancillary services exception, saying the anti-markup provision should make this unnecessary. However, the agency invited comments on whether the exception should be tightened further.

"At the time the exception was enacted," CMS noted, "typical in-office testing might have involved a lab owned by doctors and located on one floor of a small medical office building. A staff member would take a urine or blood sample to the lab, perform the test, and obtain results for the physician while the patient waited. However, services today under the exception are often not as closely connected to the physician practice."

Pathology was cited as an example. According to CMS: "Pathology services may be furnished in a building that is not physically close to any of the group practice's other offices, and the PC of the service may be furnished by contracting pathologists who have virtually no relationship with the group (in some cases, the TC is furnished by lab technologists employed by an entity unrelated to the group). Members of the group practice and their staff are never physically present in the contractor pathologist's office. Similar, the contractor pathologists do not take part in any group practice activities, attending no meetings (except for phone calls about individual patients), and do not obtain retirement or health benefits from the group. In sum, these types of arrangements appear to be nothing more than enterprises established for the self-referral of designated health services (subject to the Stark physician referral ban)."

Pathology 'Grandfather' Protection

CMS again is proposing to end billings by independent clinical labs for the technical component of pathology services to hospital inpatients and outpatients, as of January 1, 2008. Currently, "grandfathered" labs may bill Part B for TC services to these patients under a one-year congressional reprieve due to expire at the end of this year.

Congress has repeatedly stepped in to block CMS from adopting the new policy, and bills that would make the "grandfather" protection permanent are currently pending before the House Ways & Means health subcommittee (H.R. 1105) and the Senate Finance Committee (S. 458) (*NIR, 28, 13/Apr 23 '07, p. 6*).

The "grandfather" protection applies to hospital-lab arrangements for certain pathology TC billings in effect as of July 22, 1999, the date when CMS first proposed to eliminate these Part B billings. CMS maintains that Medicare pays for the TC as part of the hospital's DRG payment; thus, labs should seek TC reimbursement from the hospital, not from Part B.

Under CMS policy, the hospital is the "protected" entity, not the lab. Hospitals may switch labs without losing the protection; independent labs, however, cannot switch hospitals and still be protected. CMS also has defined the TC of pathology to include anatomic services, cytopathology, and surgical pathology.

The bills to make the "grandfather" protection permanent are backed by the College of American Pathologists, the American Society for Clinical Pathology, and the American Clinical Laboratory Association. Similar legislation was introduced in Congress last year, but failed to move. Congress instead extended the protection through December 31, 2007.

FDA Clears First Rapid Test for Malaria

Results of the Binax NOW test still need to be confirmed using standard microscopic evaluation.

The Food & Drug Administration has granted marketing approval to the Binax NOW Malaria Test, the first authorized U.S. rapid test for malaria, a mosquito-borne disease caused by a parasite. The test is manufactured by Binax, a subsidiary of Inverness Medical Innovations (Scarborough, ME), and is intended for laboratory use, the FDA said.

Standard lab tests for malaria require identifying parasites in a blood sample under a microscope, a difficult task that requires training and experience, the FDA noted. The Binax NOW test is significantly faster and easier to use, the agency said. You can get results in 15 minutes after a few drops of whole blood are placed on a dipstick. The test can also differentiate the most dangerous malaria parasite, *Plasmodium falciparum*, from less virulent malaria parasites. People infected with malarial parasites often experience a high fever, chills, and flu-like illness. Left untreated, they may develop severe complications and die.

Although malaria has been eliminated from the U.S. since the 1950s, it can still affect U.S. residents who travel or who work in other countries. According to the Centers for Disease Control & Prevention, there were 1,528 newly reported cases of malaria in this country in 2005, including seven deaths. Nearly all deaths can be prevented if the infection is diagnosed and treated early. "Since malaria is uncommon in this country, clinicians and lab personnel may not be accustomed to diagnosing it," said Daniel Schultz, MD, director of the FDA's Center for Devices & Radiological Health. "When used in combination with other lab tests, the Binax test provides an additional tool" for faster diagnosis and treatment.

Date Of Service Revision Would Affect Pathology TC

In the 2007 physician fee schedule rule, Medicare revised the date of service (DOS) for a clinical laboratory test that uses a stored specimen (one that is "archived" for more than 30 calendar days before testing). For tests using these specimens, the DOS generally is the date the specimen was obtained from storage.

Now, in the proposed fee schedule rule for 2008, the Centers for Medicare & Medicaid Services is proposing to make the DOS the same for the technical component of anatomic pathology services, saying that, in practice, the collection date for lab and pathology services is similar. For outpatients, the pathology TC can be paid under the physician fee schedule or under the hospital's outpatient prospective payment, CMS says.

Currently for lab tests, the DOS for stored specimens, including for use in chemotherapy sensitivity testing, is the date the specimen is obtained from storage, even when obtained less than 31 days from the date it was collected, without violating the unbundling rules as long as certain conditions are met. Among these conditions: the test is ordered by the patient's physician at least 14 days after the patient's discharge from the hospital, the specimen was collected while the patient was undergoing a hospital surgical procedure, and it would have been medically inappropriate to have obtained the sample other than during the procedure for which the patient was admitted (*NIR, 28, 4/Nov 20 '06, p. 2*).

CMS Proposes Reconsideration Process In Lab Fee-Setting

As required by law, the Centers for Medicare & Medicaid Services has codified in regulations the procedures it follows to get public input into the annual process for setting Part B lab fees for the coming year. The steps include hosting a public forum, held this year on July 16, to air recommendations on whether to use gap-fill or crosswalk methods to establish fees for new tests (*NIR, 28, 17/Jun 25 '07, p. 1*).

In the proposed Medicare physician fee schedule rule for 2008 published in the July 12 *Federal Register*, CMS says it plans to create a reconsideration process for determinations of the payment amounts for new clinical laboratory diagnostic tests. The agency said, "We would make a determination of gap-fill amounts by April 30. Interested parties would have 60 days to comment on the carrier-specific amounts. Carriers would finalize amounts by September 30 and CMS would set the national limitation amount (NLA) at the median of the amounts when we publish the final fee schedule in November." If CMS elects to reconsider the amounts and revise them, it would adjust the NLAs, based on comments received.

The reconsideration process would affect "new tests," defined as "any new test for which a new or substantially revised HCPCS code is assigned on or after January 1, 2008."

For The Record

In our June 25 issue (p. 6), we covered the final lab quality measures for blood glucose and cholesterol testing of patients with diabetes that Medicare announced in the 2007 physician quality reporting initiative (PQRI).

This is to clarify that:

— The measures are to be reported by the physician who treats the beneficiary.

— The voluntary reporting of lab test measures does not qualify for the bonus payment pool, which is available only to eligible physicians who report services covered under the Medicare physician fee schedule. These physicians are entitled to a bonus of 1.5%, subject to a cap.

The 2007 PQRI began July 1 and runs through December 31. Eligible providers can participate by simply reporting quality measure data on claims submitted to their Medicare contractor. Meantime, pathology quality measures have, for the first time, made it on the list of PQRI reporting measures, starting in 2008 (*related story, p. 3*).

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