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RTI Gets Medicare Contract For Lab Bidding Demo Design

The lab demo will have multiple winners in each of two geographic areas, with contracts up for re-bidding every three years. Services included: testing where there is no "face-to-face encounter" with a Medicare beneficiary. Services excluded: Pap smears, colorectal cancer screening

The Centers for Medicare & Medicaid Services on Sept. 30 awarded a task order contract to RTI International to design and launch a Part B competitive bidding demonstration for independent laboratory services, as required under the 2003 Medicare Modernization Act (MMA). The non-profit RTI in Research Triangle Park, NC, is one of 14 R&D master contractors that CMS invited to bid, and it's no stranger to the lab bidding arena (*National Intelligence Report, 25, 11/Mar. 22, '04, p. 4*).

Back in 1997, RTI designed for CMS a plan for a lab competitive bidding pilot, but further work got sidelined when the agency concentrated instead on major provider payment reforms required under the 1997 Balanced Budget Act. CMS did go forward, however, to meet the Act's requirements for competitive acquisition projects for durable medical equipment. These pilot programs reported reductions in pricing by 17% in Polk County, FL, and 22% in San Antonio, TX. And RTI has since won the follow-on contract to design a nationwide rollout of DME competitive bidding, as required by the MMA. ➥ *p. 2*

INSIDE *NIR*

Labs Still A Tempting Target For Medicare Cuts

With the federal deficit set to skyrocket over the rest of this decade, we're moving into a difficult budget period, says Washington, DC attorney Patrick Morrisey, and that means more political pressure to cut Medicare payments to labs and other healthcare providers. Morrisey, a former key House staffer, raised this warning in remarks at Lab Institute 2004, sponsored by Washington G-2 Reports on Sept. 29-Oct. 2 in Arlington, VA. Because of the budget squeeze, tradeoffs are inevitable between funding for the new Medicare drug benefit and payments to providers, he said.

Labs last year thwarted the return of a 20% co-pay, but still got slapped with a five-year fee freeze (through 2008), estimated to save Medicare some $9 billion. In the search for more savings, the co-pay idea could be revived, and there's also growing interest in looking at payment alternatives to the Part B lab fee schedule.

Jason DuBois from the American Clinical Laboratory Association told the Institute audience that the long-term political outlook will be dominated by 3-D's: deficit, demographics, and drugs. In the short term, more lab cuts could be on the table, he said, including the co-pay, fee schedule reductions, and competitive bidding.

In the latest on the national DME bidding program, CMS on Sept. 24 announced the establishment of a 21-member advisory committee. It includes at least eight representatives of DME vendors. The complete roster can be accessed through the CMS homepage, cms.hhs.gov

Lab Bidding Demo, *from p. 1*

RTI's project director for the lab bidding demo is John Kautter, PhD. RTI is using Palmetto GBA (Columbia, SC) as a subcontractor. Palmetto is the Medicare Part B carrier for South Carolina, Ohio, and West Virginia; it also serves as a Part A and home health fiscal intermediary and as a DME regional carrier.

CMS Committed To Open Process, Official Says

Speaking at Lab Institute 2004, which was sponsored by Washington G-2 Reports on Sept. 29-Oct. 2 in Arlington, VA, the lab demo's project officer at CMS, Linda Lebovic, MPH, MT(ASCP), said the demo process is still very much open. CMS intends to keep it that way, she continued, to accommodate input from the lab industry and other affected parties. The MMA requires only a project report by Dec. 31, 2005, she emphasized; it does not mandate a start-date or any number of sites or locations.

In work thus far, CMS has decided to initiate the pilot in two sites, Lebovic said, to be selected according to a range of characteristics such as managed care penetration and makeup of the beneficiary population. The scope of work at this point is envisioned in two phases: Phase I for development of a management plan and a demo design, and Phase II for selection of sites for an initial field run. CMS is also working on how to define lab services that don't involve a "face-to-face encounter" with the beneficiary. Resolution of this issue is expected to go a long way toward clarifying the situations and provider types that CMS will put up for competition in the pilot locales.

A Key Avenue For Input

The contractor also will establish a Technical Expert Panel, Lebovic said, to obtain advice as it designs the demo. Lab groups have been pressing for a voice on that panel and for active involvement throughout all phases of the demo, from design to analysis of results. Alan Mertz, president of the American Clinical Laboratory Association, who spoke at the same Lab Institute session as Lebovic, said his group and other organizations in the Clinical Laboratory Coalition definitely "want to be at the table," adding that the job "can't be done just by some academics."

While ACLA opposes the demo, Mertz said, it also recognizes that under the MMA, "Congress has dealt CMS a deck of cards and the agency has to play its hand." Accordingly, ACLA will work with CMS, he continued, to ensure that the demo is fair, does not hinder access, emphasizes more than just lowering reimbursement, covers the entire range of testing, and meets specific quality indicators recommended by the Coalition.

Political Dynamics Favor Lab Bidding Tryout

Since the mid-1980s, Medicare has tried in vain to get up-and-running a competitive bidding program for clinical laboratory services paid under the Part B lab fee schedule.

Each time, it's been stymied, either by lobbyists for the industry and professional groups or by internal diversion of funding to other priorities, such as provider payment reforms mandated under the 1997 Balanced Budget Act.

The 2003 Medicare Modernization Act changes that political landscape. It *requires* Medicare to come up with a design for a pilot program targeting most independent lab services.

On Capitol Hill, competitive bidding has strong backing from influential House GOP committee chairmen, Bill Thomas (CA) of the Ways & Means Committee, and Joe Barton (TX) of the Energy & Commerce Committee. They believe that injecting more competition into the Medicare program will produce not only program savings, but also wider access to high-quality services. And the quest for savings in Medicare and other domestic programs is expected to intensify next year, political analysts say, as the overall federal budget deficit worsens.

Meantime, both state officials and lab industry lobbyists are keeping a close eye on Florida's experiment with lab competitive bidding. Florida plans to award a capitated contract to a single independent lab to serve Medicaid recipients throughout the state (*NIR, 25, 21/Sep 13, '04, p. 4*). The plan is opposed by national lab trade groups and by a consortium of smaller independent labs based in the state. At press time, observers predict, Florida Medicaid's "invitation to negotiate" should be coming out any time now. There has been speculation that if successful, the Florida gambit could become a template for other states and even Medicare.

Medicare Urged To Add More Tests To New Screening Benefits

Clinical laboratory and pathology groups want the Centers for Medicare & Medicaid Services to reimburse more tests under the screening benefits added by the Medicare Modernization Act of 2003 and to do it more frequently than the agency has proposed. The agency listed four cardiovascular test codes and two diabetes test codes in its Medicare physician fee schedule proposal for 2005 (*NIR, 25, 20/Aug. 16, '04, p. 1*). The new covered screening for heart disease, diabetes, and a baseline physical exam for new beneficiaries is effective Jan. 1, 2005.

Heart Disease Screening

The American Society for Clinical Laboratory Science argued that CMS should not make everyone wait five years between cardiovascular screening tests. The association said that those with diabetes risk factors such as cigarette smoking, hypertension, and obesity should get screened for cardiovascular disease every two years. The American Clinical Laboratory Association also called for greater frequency.

ASCLS urged CMS to add the test for high sensitivity C-reactive protein (hsCRP) to the list of covered cardiovascular screening codes, even though the U.S. Preventive Services Task Force has not recommended it. ASCLS noted that in the years since the task force issued its latest guidance, in 2001, a "significant body of literature has been published" indicating that hsCRP is important in assessing a person's risk of heart disease. The association suggested that if CMS does not approve hsCRP for screening, then it should immediately request a formal review by the task force.

Tallying Up The Screening Tab

According to CMS's regulatory impact analysis, the new screening benefits added by the Medicare reform law will result in major new costs to the Medicare program over the five-year period beginning in 2005:
—Cardiovascular screening, $410 million
—Diabetes screening, $250 million
—"Welcome to Medicare" exams and follow-up for new beneficiaries, $365 million.

How much does other screening reimbursed under the Part B lab fee schedule cost? *NIR* compiled these figures from CMS carrier data for 2002:

HCPCS Code/Descriptor	*Allowed Services*	*Allowed Charges*
G0103, PSA test	1,228,473	$31,100,906
G0107, Fecal occult blood	1,782,707	7,769,199
P3000, Screening Pap smear	501,496	7,276,941
G0123, Screening Pap smear	642,879	17,444,444
G0143, Screening Pap smear	19,568	544,832
G0144, Screening Pap smear	65	1,801
G0145, Screening Pap smear	8	197
G0147, Screening Pap smear	2,827	43,558
G0148, Screening Pap smear	21,003	395,079
Total	4,199,026	$64,576,957

ACLA applauded CMS' approach to coding the new screening tests, while urging greater flexibility. In the past, the agency typically created a HCPCS code for screening tests, while using a different CPT code to indicate diagnostic use. This led some carriers to deny claims with the wrong pair of codes, a common mistake. Under the new approach, CMS would use existing CPT codes for diagnostic tests, but link them to specific ICD-9 codes to indicate they were performed as a Medicare-covered screening test. However, ACLA noted that under its National Coverage Decision (NCD) for lipid tests, CMS lists a number of other ICD-9 codes to disallow the testing for screening purposes. CMS should include those codes for the new screening tests to avoid confusion, ACLA said.

Diabetes Screening

ASCLS urged CMS to allow twice-a-year screening of all Medicare beneficiaries, not just those diagnosed with pre-diabetes, saying it would be an administrative

burden to limit frequency to once a year for those without pre-diabetes. ACLA urged CMS to approve screening tests involving any of the ICD-9 screening codes listed in the diabetes NCD for diabetes tests performed for diagnostic purposes.

Meanwhile, the College of American Pathologists asked CMS to add CPT 82950–Glucose; post glucose dose (includes glucose)—to the list of covered diabetes screening codes, because it is used more frequently for screening than a code CMS did include—82951, Glucose; tolerance test (GTT). CAP said the latter is more of a definitive test used when results from tests of random, fasting or post-glucose dose or postprandial glucose levels are questionable.

CLIAC Aims To Improve Quality In CLIA-Waived Labs

Alarmed by continued findings of quality shortfalls at labs operating under a CLIA certificate of waiver, the Clinical Laboratory Improvement Advisory Committee has set up a workgroup on good laboratory practices for waived testing. The workgroup will report back at CLIAC's next meeting in February 2005.

At last month's CLIAC meeting (held Sept. 22-23 by the Centers for Disease Control & Prevention in Atlanta, GA), officials of the Centers for Medicare & Medicaid Services presented updated findings on quality problems that CMS uncovered in 2002 in its survey of 897 CLIA-waived labs. CMS's top CLIA official, Judy Yost, had presented preliminary findings at the CLIAC meeting last February (*NIR, 25, 9/Feb. 23, '04, p. 4*).

Devery Howerton, PhD, chief of CDC's Laboratory Practice Evaluation and Genomics Branch, told CLIAC members that Medicare spent $3.2 billion on 266.8 million waived tests in 2003, up from $2.3 billion on 225 million waived tests in 2000. The most commonly performed waived tests are glucose, dipstick urinalysis, fecal occult blood, urine pregnancy, and Group A streptococcal antigen.

The bottom line, a CMS official said, is that "serious quality problems do exist in certificate-of-waiver (COW) facilities." In the first of what the agency hopes will become a permanent survey of a small percentage of COW labs each year, CMS found cause for concern about training. The labs surveyed—which included 45% in physician offices and 12% in nursing homes—were typically manned by nurses, physicians, medical assistants or high school graduates, not laboratorians, noted Daralyn Hassan, MS, MT (ASCP) and Raelene Perfetto, MBA, MT (ASCP), both of CMS.

Hassan and Perfetto added that of the 897 COW labs surveyed in 2002:

- ❑ 44% had new testing personnel.
- ❑ 8% tested beyond the scope of their waiver certificate.
- ❑ 14% lacked current manufacturer instructions.
- ❑ 24% did not perform quality control as required by the manufacturer.
- ❑ 13% used the wrong units in reporting test results.
- ❑ 7% did not use the proper expiration data for their storage method.
- ❑ Two put beneficiaries in immediate jeopardy.

CMS surveyed 1,756 labs in 2003, with similar preliminary results. CMS is continuing to gather and analyze COW lab survey data for 2003 and 2004. CLIAC plans to use the agency's COW quality data in support of an article to be submitted to CDC's *Morbidity and Mortality Weekly Report*, for possible publication next year.

Quality vs. The "No Lab Left Behind" Program

James O. Westgard, *PhD, was the recipient of the 2004 annual Laboratory Public Service National Leadership Award, honored for his lifetime achievement in setting quality standards that are followed worldwide. Dr. Westgard currently is a professor in the Dept. of Pathology and Laboratory Medicine at the University of Wisconsin Medical School and president of Westgard QC Inc., both in Madison. Below are his remarks upon acceptance of the award.*

The award was presented Sept. 30 during the annual Lab Institute, sponsored by Washington G-2 Reports and held in Arlington, VA. In introducing her colleague, Teresa Darcy, MD, who chaired the independent award selection committee, praised his quality design concepts "recognized in every clinical lab in the world" and "his ability to translate innovative research into widespread use through his teaching and publications."

It is a great honor to receive an award that recognizes one's lifetime work. And no one's work is really all their own. I have many people to thank, especially two who are here today—my boss at work and good friend, Teri Darcy, and my boss at home and good friend, Joan Westgard.

Few people have the luxury of focusing their entire career on a single issue, like quality in laboratory testing. I am one of those fortunate few. This was made possible by the University of Wisconsin, one of the great land-grant universities in this country, a government institution that has made the American dream a reality for people like me.

Garrison Keiller tells the story best in his recent book, *HomeGrown Democrat*. He speaks of the University of Minnesota, another land-grant university, with great reverence because of the opportunities it provided. His story of growing up in a Midwestern Scandinavian community is the story of many Midwesterners, myself included.

I consider myself to be a "Minnesotan." While I grew up in North Dakota and have spent most of my adult life in Wisconsin, when people ask me where I'm from, I always say, "on average, Minnesota." And while that answer may cause you to distrust my statistical skills, it does represents the truth. I am truly one of the citizens of that little town called Lake Wobegon where the "women are strong, the men are good-looking, and all the children are above average."

People sometimes wonder how all the children can be above average, and I tell them it's a government program called public education. Unfortunately, public education today is under attack. While there is a new program called "No Child Left Behind," that program has been misdirected by an emphasis on testing and grading. If you test selectively, if many states lower the standards, then everyone can be above average. That's what's happening throughout the country right now.

Equally disturbing is a similar program that is being introduced to improve the grades for healthcare laboratories. The Centers for Medicare & Medicaid Services has documented that 5-10% of laboratories still show serious deficiencies in quality control and quality assurance. In an attempt to reduce these deficiencies, the government has introduced the "No Lab Left Behind" program, otherwise known as "equivalent QC."[1] If CMS can't get labs to run two controls per day, then maybe they can get them to run two per week or two per month. That should certainly improve the compliance grades. Unfortunately, it won't improve the quality of laboratory testing. And quality is still an issue, as revealed by the Maryland General Hospital incident this past year.[2]

The government considers the incident to fall into the category of a "few bad apples." The "bad apple" theory has been widely asserted as the explanation for other serious problems, such as the Abu Ghraib prison scandal. The commonality should be very disturbing to everyone, and particularly to people with experience in quality management. It is fundamental to quality management to recognize that problems are due to management deficiencies, not the behavior of individual workers. When management assigns the lowest skilled workers and provides only minimal on-the-job training, and things go wrong, management is responsible for what goes wrong. The reason is that management itself is the only one who could have prevented the problems from occurring by proper planning and implementation.

The difficulty in dealing with quality is that it is a complex value, much like truth. It's not enough to tell a little bit of the truth. Laboratory tests must tell the truth, the whole truth, and nothing but the truth. The "nothing but the truth" part requires assuring the absence of complicating factors that might otherwise destroy the validity of the test results, such as the method being out-of-control. Less QC will not improve the quality of laboratory tests! Equivalent QC will only result in better grades for compliance. Unfortunately, compliance isn't the same as quality. Compliance is about avoiding penalties and staying out of jail; quality is about satisfying the needs of patients for medically reliable test results. Quality is about patient care and patient safety!

There is a need for new leadership in this country if truth and quality are to once again become public values. It must start at the top of our government and spread through all our businesses and professional organizations to all the individual healthcare workers. When truth and quality are truly valued, healthcare will become focused on excellence, not just compliance.

Editor's Note: Footnotes added to refer readers to coverage in our newsletters of the issues cited by Dr. Westgard, who also posts his views and educational/training materials online at *www.westgard.com*.

[1] *G-2 Compliance Report*, Apr. 2004, pp. 5-8.
[2] *NIR*, June 7, 2004, pp. 4-6.

Medicare Urged To Crack Down On "Pod" Labs

In remarks bristling with legal references that federal prosecutors might tap to move against "pod" labs, clinical laboratory and pathology groups are urging the Centers for Medicare & Medicaid Services to crack down on what they regard as abusive business arrangements. The groups registered their concerns in comments filed with CMS on the proposed 2005 Part B physician fee schedule.

"Pod" labs are a new and spreading phenomenon in the medical marketplace, enabling specialty physicians to increase their Medicare revenue by tapping into pathology referrals to labs they operate (*NIR, 25, 18/Jul 5, '04, p. 4*). Compliance experts warn that such arrangements pose significant fraud and abuse risk under both the Stark self-referral law and the Medicare anti-kickback statute. The HHS Inspector General's Office has already voiced its suspicions about these ventures, citing their potential to overutilize services and thus cause more unnecessary Medicare spending (*NIR, 25, 17/Jun 21, '04, p. 1*).

In its comments to CMS, the American Clinical Laboratory Association recommends adding a Section 424.80(d)(3) to the fee schedule, clarifying that "a contractual arrangement for the provision of pathology services will be deemed the purchase of purchased diagnostic tests(s) and purchased interpretation(s) of diagnostic tests, and the arrangement must comply with the requirements applicable to such tests and interpretations."

In challenging "pod" labs, ACLA has already asked CMS to tighten the Stark self-referral exception for in-office ancillary services and now wants the agency to reconsider its interpretation of Section 952 of the Medicare Modernization Act which made major exceptions to the ban on reassignment of benefits. According to ACLA, Section 952 was meant to address a specific problem that the General Accounting Office had targeted in a March 2003 report (GAO-03-185); namely, CMS's inability to monitor hospital emergency room staffing companies because the reassignment rule prevented them from enrolling in Medicare. However, because CMS could not distinguish between their physician contractors and other independent contractors, Congress wrote Section 952 too broadly, in ACLA's opinion, appearing to allow arrangements that "give physicians a financial interest in their own test-ordering." CMS failed to resolve conflicts between the reassignment relaxation and the Stark law when it issued Transmittal 111 to implement Section 952, ACLA said, though the agency did raise fraud and abuse concerns in its proposal for the 2005 physician fee schedule.

ACLA pointed out that the Medicare Claims Processing Manual, in Chapter 1, Section 30.2.9, bars physicians who purchase diagnostic tests from marking up the amount pathologists charge them for the technical component, and in Chapter 1, Section 30.2.9.1, forbids physicians or groups who triggered the referral from billing Medicare for the professional component.

Inside The "Pod" Lab

In a typical case, a non-pathology medical practice—such as one in gastroenterology, urology, and dermatology—establishes an in-house histology lab. The practice hires a facility manager who divides leased space in a medical building into separate cubicles or rooms, each subleased to a specialty group. Each cubicle gets its own microscopes and other laboratory equipment.

The lab shares a histologist, who provides technical services, and a pathologist, who interprets and supervises the testing. The pathologist usually works under contract with the specialty group, and the manager usually hires the histologist. They move from room to room, preparing and interpreting anatomic pathology specimens.

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

NCQA Cites Quality Strides Among Reporting Healthcare Providers

Participating health plans registered among the greatest gains ever in healthcare quality in 2003, including higher rates of clinical laboratory testing for key performance measures, the nonprofit National Committee for Quality Assurance (Washington, DC) reported Sept. 23. But the improvement was limited to the 563 health plans (generally HMOs and point-of-service plans) that reported their Health Plan Employer Data & Information Set (HEDIS) results to NCQA last year. These plans cover some 69 million Americans. The best available data showed no significant improvement for the system as a whole.

If all health plans could match the performance of the top 10%, this would prevent 42,000 to 79,000 avoidable deaths a year, $1.8 billion in hospital costs, and 66 million sick days, valued at $9.6 billion, estimated NCQA. "The data we have tell a great story—quality for some is improving … But we have data only for accountable health plans. Why don't we have [it] for the other 75% of the U.S. healthcare system? All types [of providers] … should report on their performance," said NCQA president Margaret O'Kane

More health plans are choosing to report their HEDIS quality data, most notably CIGNA HealthCare, the first national health plan to join, which will begin reporting PPO performance in 2006. Also, some physicians and hospitals are beginning to report their performance, driven in part by new incentives. A number of private-sector initiatives have begun rewarding providers for quality, based on the HEDIS performance measures. The Centers for Medicare & Medicaid Services is also seen as a leading player in moving the healthcare system toward paying for performance—it began making higher Medicare payments, as of Oct. 1, to hospitals that voluntarily reported quality indicators (*NIR, 25, 22/Sep 27, '04, p. 4*).

Over the past four years, cholesterol screening after heart attacks has increased by 13.9% for Medicaid, 10.4% for Medicare, and 6.1% for commercial plans, NCQA indicated. Meantime, HbA1c testing of diabetics has increased by 6.3% for Medicaid, 6.2% for commercial plans, and 5.4% for Medicare. Key lab-related HEDIS measures in 2003 were:

Measure	***Commercial***	***Medicaid***	***Medicare***
Appropriate Testing for Children with Pharyngitis*	70.7%	53.8%	N/A
Cervical Cancer Screening	81.8	64.0	N/A
Chlamydia Screening (ages 16-20)	30.4	44.3	N/A
Chlamydia Screening (ages 21-25)	29.1	46.0	N/A
Cholesterol Management After Acute Events (Screening)	80.3	57.7	81.0
Colorectal Cancer Screening*	47.4	N/A	49.5
Comprehensive Diabetes Care (HbA1c Testing)	84.6	74.8	87.9
Comprehensive Diabetes Care (LDL-C Screening)	88.4	75.9	91.1
Comprehensive Diabetes Care (Nephropathy)	48.2	43.7	53.6
Comprehensive Diabetes Care (Poor HbA1c Control)**	32.0	48.6	23.4

*New measure for 2003. ** Lower rates are better for this measure.

For more details, see "The State of Health Care Quality: 2004" at: *http://www.ncqa.org/communications/SOMC/SOHC2004.pdf.*

Making The Medicare Coverage Process More Open & Faster

In Section 731 of last year's Medicare Modernization Act, Congress required the Centers for Medicare & Medicaid Services to expedite and make more transparent its methods for arriving at Medicare coverage determinations for medical innovations, including new diagnostic tests and technologies.

In response, CMS has published, in the Sept. 24 *Federal Register*, a notice that it plans to issue guidance documents similar to those issued by the Food & Drug Administration. The guidance should, CMS said, help technology developers, patient advocates, and other interested parties learn more about the likely implications of requesting a legally binding National Coverage Decision, as well as clarify what information an NCD request should contain and how CMS evaluates various types of evidence in reaching a "necessary and reasonable" coverage determination.

Plus, CMS observed, the guidance "may be useful in certain cases to help plan investment strategies, R&D efforts, and marketing and clinical diffusion strategies."

In a Sept. 30 open-door forum, CMS administrator Mark McClellan, MD, PhD, said the guidance documents will, "when appropriate," help the agency find ways to more quickly reimburse FDA-approved technologies. The documents will be posted online at *cms.hhs.gov/coverage*.

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