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Deficit Woes Add New Pressure on Medicare Spending

While Part B lab fees are due to increase next year after a five-year freeze, many clinical labs face demands from large private payers for services at prices well below Medicare in exchange for volume.

With the federal deficit skyrocketing, Congress will come under intense pressure next year to look to the Medicare budget to lower government spending. That poses a big potential threat to clinical laboratory fees, Alan Mertz, president of the American Clinical Laboratory Association, warned at Lab Institute 2008, held Sept. 17-19 in Arlington, Va.

The industry's legislative priority, he said, is to maintain a united front—as proved successful this year in repealing the lab competitive bidding demonstration—to forestall any move to cut Part B lab spending to pay for fee increases elsewhere in Medicare. More than half (54.6 percent) of those polled in a pre-Institute survey agreed.

Topping next year's Part B agenda is a Medicare physician fee fix to prevent a steep payment cut in 2010 and beyond. Congress this year canceled a 10.6 percent fee cut and approved a 0.5 percent increase, but it expires Dec. 31, 2009.

Despite the current financial straits, health care reform is not off the legislative table, noted several speakers at the Institute, who said reform remains a major public concern due to rising costs and millions more Americans who have lost or are at risk of losing job-related health insurance coverage. For more on these and other policy issues examined at the Institute, see the *Focus*, pp. 4-7.

CMS Offers Labs a Customized Choice For New Advance Beneficiary Notice

In announcing the required use of a new single-page Advance Beneficiary Notice (ABN) starting March 1, 2009, the Centers for Medicare and Medicaid Services also unveiled a version tailored to clinical laboratory use.

The new approved versions of form CMS-R-131 replace three notices currently in use: the general ABN-G, the lab-specific ABN-L, and the Notice of Exclusion From Medicare Benefits, CMS noted in manual instructions released earlier this month (*NIR, 29, 21/Sep 15 '08, p. 1*). The ABN must be used to alert Part B fee-for-service beneficiaries when they may be financially liable for an item or service that Medicare is likely to deny.

The lab customized version differs from the general CMS-R-131 in the layout of the grid to help a beneficiary match *Continued on p. 2*

INSIDE *NIR*

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Clinical laboratories and other providers billing Part B may switch to the revised single-page ABN at any time but must start using it as of March 1, 2009.

Advance Beneficiary Notice, *from p. 1*
a listed or checked testing service, the reason Medicare may not pay, and the estimated cost of the service. Instead of the headers for these three sections running across the page, the lab version has them stacked in a column running down the left side (*p. 3*).

As long as the required language and general formatting of the ABN are not altered, labs may further modify the form by preprinting company logos with the name, address, and telephone number (including TTY number when needed) at the top of the notice or by preprinting common reasons for noncoverage (as long as they indicate which portions apply or do not apply to the beneficiary). Also multiple versions may be specialized for common treatment scenarios. The form should always identify who should be contacted when questions arise, CMS noted.

ABNs may be customized or modified only as allowed in the manual instructions, and the CMS Regional Office must approve the changes or the provider risks having an invalid ABN and being liable for noncovered charges.

Drilling Down to the Details

In the manual instructions, CMS is specific about the ABN's size, print, and look:

- *Length:* The ABN may not exceed one page. Attachments are permitted for additional services; if used, note this in the grid listing the service, estimated cost, and why Medicare may not pay.
- *Languages:* CMS-approved ABNs are available only in English and Spanish. Insertions on either must be in the language of the form used. Translation assistance in other languages should be documented in the "Additional Information" section.
- *Print:* Text should be dark ink on a pale background. No reverse print or block-shaded print.
- *Fonts:* Use the fonts on the CMS-approved form or those that are easily readable, such as Arial, Arial Narrow, Times New Roman, and Courier. Font size for body copy should be 12 point; titles, 14 to 16 point. Insertions in the blanks on the form can be as small as 10 point if needed.
- *Copies:* Have a minimum of two copies—one for the beneficiary, one for the provider. The provider should keep the original wherever possible.
- *Retention:* Keep the ABN for five years from discharge or completion of the delivery of care when there are no other applicable requirements under state law.

Special Issues in Delivering the ABN

What if the beneficiary changes his or her mind after completing an ABN? The provider should give it back and ask him or her to annotate it, CMS said, indicating the beneficiary's new option selection along with his or her signature and the date of annotation. When unable to present the ABN in person, the provider may annotate the form to reflect the beneficiary's new choice and immediately forward a copy to him or her to sign, date, and return. If a related claim has been filed, it should be revised or canceled to reflect the new choice.

What if the beneficiary refuses to choose an option or sign the ABN? The provider should annotate the original, indicating the refusal to sign and may list any witnesses, though this is not required. "If a beneficiary refuses to sign, the provider should consider not furnishing the service unless the consequences (the health and safety of the patient or civil liability in case of harm) are such that this is not an option," CMS noted.

Notifier(s):
Patient Name: **Identification Number:**

ADVANCE BENEFICIARY NOTICE OF NONCOVERAGE (ABN)

NOTE: If Medicare doesn't pay for items checked or listed in the box below, you may have to pay. Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the items listed or checked in the box below.

Listed or Checked Items Only:			
Reason Medicare May Not Pay:			
Estimated Cost:			

WHAT YOU NEED TO DO NOW:

- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the checked items listed in the first box above.

Note: If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this.

Options: Check only one box. We cannot choose a box for you.

- ❑ **OPTION 1.** I want the _____listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but **I can appeal to Medicare** by following the directions on the MSN**.** If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.
- ❑ **OPTION 2.** I want the _____listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. **I cannot appeal if Medicare is not billed**.
- ❑ **OPTION 3.** I don't want the _____ listed above. I understand with this choice I am **not responsible for payment,** and I cannot appeal to see if Medicare would pay.

Additional Information:

This notice gives our opinion, not an official Medicare decision. If you have other questions on this notice or Medicare billing, call **1-800-MEDICARE** (1-800-633-4227/**TTY**: 1-877-486-2048).
Signing below means that you have received and understand this notice. You also receive a copy.

Signature:	**Date:**

Form CMS-R-131 (03/08) **Form Approved OMB No. 0938-0566**

focus on: *Lab Institute 2008*

Lab Industry Urged to 'Get Ahead of the Wave'

While battling against reimbursement cuts and pushing for better payment for genetic testing to maximize this market, the clinical laboratory industry should go on the offensive for growth and get ahead of the wave of fundamental changes in the health care landscape, said Dennis Weissman, program chairman, at the opening of the 26th annual Lab Institute held Sept. 17-19 in Arlington, Va.

Pointing to a major political realignment with the rise of the millenial generation and the expansion of health information technology, "both government and consumers will play a larger role, not only in paying for health care, but also in how they are wired into the system," he said.

Rise of the Millenial Generation

The generation born since 1982 is the coming new powerhouse in politics, economics, and health care policy, said keynote speakers Morley Winograd and Michael D. Hais, authors of *Millenial Makeover: MySpace, YouTube & the Future of American Politics*.

The nation has had four decades of electoral dominance by one party ending with a brief but decisive realignment, they noted, with minimal change in party identification, voting coalitions, and public policy, but the millenials represent the political coming-of-age of a large, dynamic generation armed with emerging communications technology using Web-based social networking sites.

There are now one million more millenials alive than baby boomers and twice as many millenials as Generation X, Winograd and Hais noted. Almost 40 million millenials will be eligible to vote this year, they added.

As a group, millenials are the largest and most ethnically diverse generation in American history; 40 percent are African American, Hispanic, Asian, or of mixed race. They are not ideological and not superpartisan. They are more interested in building civic institutions and infrastructure and will support solutions that are workable.

While not yet in the majority, they soon will be. In health care policy, they favor a government role in setting rules and guidelines, including a ban on use of pre-existing conditions in underwriting, greater transparency on cost and quality, and guaranteeing health insurance for all citizens even if it means raising taxes. At the same time, they want solutions that allow as much choice as possible.

Market Profile

- More than 4,000 laboratory tests are available.
- 1,162 tests are covered by Medicare.
- 500 are performed regularly.
- More than 200,000 labs are CLIA-registered.
- 106,000 are physician office labs (POLs).
- Approximately 80 percent of POLs are certified to perform only waived and/or provider-performed microscopy tests.
- The number of CLIA-waived tests is increasing—338 million were performed in 2006, or 13 percent of all lab tests.
- Approximately 1,430 conditions are currently detectable using genetic testing; 287 are tested only in research settings.
- Over-the-counter (OTC) and direct-to-consumer testing is on the rise, with 35 lab test types sold OTC.

Presentation at Lab Institute by Julie R. Taylor, Ph.D., CDC division of lab systems in the coordinating center for infectious diseases.

Good News for Labs, Pathologists

At the Institute's Capitol Hill Buzz session, Alan Mertz, president of the American Clinical Laboratory Association, noted that clinical lab and pathology groups scored on three top legislative priorities this year:

- ❑ Repeal of the Medicare competitive bidding demonstration for independent lab services that the government had planned to launch July 1 in San Diego.
- ❑ Increase in Medicare fees. Congress canceled a 10.6 percent cut in physician fees and guaranteed a 0.5 percent increase through 2009. Lab fees got a Consumer Price Index (CPI) update for the first time in five years; however, Congress reduced the update by 0.5 percent from 2009 through 2013. The update for 2009 is 4.5 percent.
- ❑ Extension of the "grandfather" protection that allows certain independent labs to bill Part B for the technical component of anatomic pathology services for hospital patients.

The Bad News

The nation's financial picture only adds to the squeeze on Medicare spending, Mertz said, and urged labs to remain vigilant against any legislative move to cut lab spending to pay for increases elsewhere. He emphasized the importance of a solid front to safeguard lab spending, noting the industry's success in persuading Congress to scuttle the lab bidding demo. Advocacy campaigns must continue to educate members of Congress and their staff on the value of lab testing in clinical practice and the need for better reimbursement for new genetic tests and technologies, he said.

In comments to *NIR*, Weissman noted the innovative strategy used by the industry to defeat competitive bidding. Instead of going through the health committees on the Hill, the industry took the small business route, where the bidding demo would wreak the most havoc by forcing local labs out of business and limiting access for beneficiaries.

For pathology and other physician groups, the coming year means another concerted push for a long-term Medicare fee fix, with Congress on the hook to decide how to pay for it. The current fee hike is only an interim fix, and medical groups want lawmakers to avoid more "Band-Aid" approaches. The

2008 Lab Public Service National Leadership Award

Award Goes to Lab Bidding Foe, U.S. Rep. Nydia Velázquez

At a special ceremony during Lab Institute 2008, Congresswoman Nydia Velázquez (D-N.Y.) accepted the Washington G-2 Reports award honoring her distinguished work in public policy affecting the clinical laboratory industry from Kevin Ellison, president of Kellison & Company, which sponsors the award.

Velázquez, who chairs the House Committee on Small Business, was honored as the first legislator to cast national scrutiny on the Medicare lab competitive bidding demonstration and its adverse impact on local labs and beneficiaries, including vulnerable populations in rural areas and nursing homes. She took the lead by holding hearings on the issues and, based on the findings, introduced legislation, H.R. 3435, to repeal the demo. The bill was ultimately incorporated into a broader Medicare package that became law July 15 when Congress overrode a presidential veto.

Velázquez is currently serving her eighth term as Representative for New York's 12th Congressional District, which encompasses parts of Brooklyn, Queens, and the Lower East Side of Manhattan. It is the only triborough district in the New York City congressional delegation.

She has made history several times during her tenure in Congress. In 1992, she was the first Puerto Rican woman elected to the U.S. House of Representatives. In 2006, she was named Chairwoman of the Small Business Committee, making her the first Latina to chair a full congressional committee. The Small Business Committee has oversight of federal programs and contracts totaling $200 billion annually. She also serves on the House Financial Services Committee.

groups want repeal of the current Sustainable Growth Rate (SGR) formula used to calculate annual updates. Unless lawmakers intervene, the SGR triggers a negative update in 2010.

Prospects for Health Care Reform

While policymakers and the public grapple with financial turmoil in the markets, the nation's health care system also is in crisis, due to rising costs and the growing number of Americans at risk because they are uninsured or underinsured. How will Congress address the long-bubbling issue of health care reform?

This question was tackled at the Institute by Maggie Mahar, Ph.D., health policy fellow at The Century Foundation, and Grace-Marie Turner, president of The Galen Institute. Turner said we can expect to see action on health care reform next year, but the issue will not be front and center. "There are too many competing priorities—the economy, the wars in Iraq and Afghanistan, and energy. There also is not much money on the table, so the changes will likely be incremental."

Mahar also did not see broad health care reform on the horizon next year, but rather more emphasis on raising quality and expanding pay-for-performance and other value-purchasing approaches to help lower costs in Medicare. Response to demographic changes will also drive the way Medicare pays for care. The number of the aging is growing, they have a longer life expectancy, and they are more likely to have chronic conditions such as cancer, diabetes, and congestive heart failure. Roughly 80 percent of program spending goes for this population, so the government will be looking at value, quality, and improved outcomes in this area.

Where are the growth opportunities in the lab market? Multiple speakers at the Institute pointed to molecular and other high-end esoteric testing. This, not routine lab work, is the fastest growing market segment, they said, noting that new clinical lab and anatomic pathology companies offering this specialized testing have attracted venture capital investment.

Advances in lab testing technology have created a 'hot' market for genetic, proteomic, and pharmacogenomic testing. Policymakers have taken note. The Food and Drug Administration has already expanded its oversight of a category of genetic testing known as IVDMIAs. Lab industry groups have warned against overregulation that could strangle innovation. Direct-to-consumer marketing of genetic tests also is a growing policy concern. Federal and state regulators as well as direct-sell companies are grappling with how best to assure quality, proper interpretation of results, and the individual's understanding of the test's benefits and limits without unduly curbing his or her choice to have the testing performed.

Market forces alone cannot fix the health care system, Mahar said. In most markets, consumers have the power to influence quality and price by comparison shopping. In health care, they do not have this leverage. Nor are they bargain hunters. "If you need a service, you will pay for it no matter what. When your life or that of a family member is threatened or when a condition causes pain and suffering, you will pay for it no matter what. No one wants discount surgery, even for a procedure like a knee replacement."

In the current system, the usual rules of supply and demand do not apply, she said. "Supply drives demand." For example, hospitals compete for well-paying patients and feel that to do so they must have the newest procedures and equipment. "They pay for it by using it." Physicians tend to utilize more services to counter the inherent ambiguity and uncertainty in medicine. "Will this treatment help? In many cases, the answer is "It depends." Further, it is often easier to treat a patient in the hospital than at home because there are specialists on call, Mahar noted. But studies show that outcomes are no better in aggressive supply-driven care, and often such care results in more mortalities from hospital-acquired infections and medication errors.

The only way to rein in cost is by government regulation, she concluded. "Look at a service, what it is known to do, and what should be paid for it." Medicare already

sets a price for its covered services and is moving toward comparative effectiveness approaches in deciding how to establish or adjust a price. Sen. Barack Obama (D-Ill.) has proposed an institute to examine comparative effectiveness research and its application to federal programs. "This is a good start. Studies of this are controversial because head-to-head comparisons mean winners and losers, and who wants to lose when so much money is at stake?"

The presidential candidates of the major political parties agree on the need for more choices of coverage at affordable rates, but differ over how to bring costs down and expand access. Obama favors a larger role for government, while rival Republican Sen. John McCain (Ariz.) backs more competition in the private insurance market.

Can ground be found for compromise? Yes, said Turner. "Quality is not controversial. It would be a good place to start. The aim is to getter better value for health care dollars, though it will not necessarily be cheaper at the start. Other points for compromise include emphasis on preventive care and better disease management as well as adoption of electronic health records."

In Turner's view, the question is, how do we subsidize coverage from a tax standpoint in the private market? Medicare expansion is not an option, she said, because its costs already are unsustainable over the long term. Health care reform should be guided by the following principles, she said: "Build in value, more affordability, more choice, so consumers can get the same benefit in the individual or group market that they do in job-based coverage." Choice is very important, she noted. "The lab industry has had a brush with competitive bidding where the government picks winners and losers and create monopolies."

Mahar said that McCain's approach was "every man for himself. You get a tax credit and lots of choices. You are free to choose what you can afford. The cheapest choices will be 'Swiss cheese' coverage, and you will feel the holes when you get sick."

Asked from the audience about how health care reform can improve the health of the nation, Mahar said health care is only about 10 percent of the effect. "The biggest impact comes from the environment, about 30 percent; income, 25 percent; and behavior, 30 percent … Poverty is the real reason for poor outcomes in childbirth and other treatable conditions. Obesity, for example, is concentrated in low-income populations for whom the healthiest foods are the most expensive. We need another War on Poverty as we had under President Lyndon Johnson to correct this."

G-2 Scholarship Awarded to Saint Luke's Hospital CLS Program

The fifth annual Dennis Weissman/Washington G-2 Reports' Scholarship, sponsored by McKesson, was awarded to Saint Luke's Hospital Program (Kansas City, Mo.) for excellence in clinical laboratory science (CLS), and Maureen O'Dowd was on hand at Lab Institute 2008 to receive the $5,000 award on behalf of her class from Bob Weathers, vice president for laboratory services at McKesson.

Saint Luke's CLS program has maintained continuous accreditation since 1936, and last year was reaccredited through 2014 by the National Accrediting Agency for Clinical Laboratory Sciences. The program accepts students in their final undergraduate year or those with a relevant scientific undergraduate degree. The curriculum encompasses 11 months of clinical experience in the hospital-based reference laboratory, plus a community service component.

The CLS class of 2009 has a combined average undergraduate GPA of 3.3 on a 4.0 scale, and includes, in addition to O'Dowd from Rockhurst University: Danielle Cole, University of Arkansas at Pine Bluff; Jessica Conrath, Jessica Heenan, and John Wilson, University of Missouri-Kansas City; Adam Downing, Northwest Missouri State University; and Ben Whitney, Kansas State University.

CMS Announces Ninth New MAC Award

The Centers for Medicare and Medicaid Services has selected First Coast Service Options, Inc. (FCSO), based in Jacksonville, Fla., to handle combined Medicare Part A and Part B claims processing for clinical laboratories, pathologists, and other health care providers in Florida, Puerto Rico, and the U.S. Virgin Islands.

This is the ninth of 15 competitively bid A/B contracts that CMS will award in the transition to the Medicare Administrative Contractor (MAC) system by 2011, replacing fiscal intermediaries and carriers. As the MAC for Jurisdiction 7, FCSO will take over the combined work incrementally and assume full responsibility for it by no later than March 2009, CMS said. The contract has an approximate value of $368 million over five years. The workload accounted for 8.4 percent of national Medicare fee-for-service claims as of September 2007.

Providers, Beneficiaries Affected

— 3,765,918 Medicare fee-for-service beneficiaries as of July 2007.
— 298 Medicare hospitals as of December 2007.
— 76,754 physicians and practitioners as of July 2007.

Meantime, in a Washington G-2 survey prior to this month's Lab Institute, 47 percent of those polled cited adapting to the MAC environment as their greatest regulatory challenge in the coming year.

Upcoming G-2 Events

Register now and get more information on the events and speakers, as well as CD recordings if you cannot attend, at www.g2reports.com

Audio Conference
Oct. 21: How to Achieve Cost Savings for Your Lab by Analyzing Test Utilization Patterns
Discover how to save hundreds of thousands of dollars every year by identifying and eliminating expensive tests of little or no clinical value. But this analysis is complicated. Better test utilization requires a careful balance of saving through paring down a test menu, while at the same time not eliminating tests that are important to your clients.

Institute Program
Oct. 20-22: 2nd Annual Diagnostic Imaging Institute, Westin Arlington Gateway Hotel, Arlington, Va.

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