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Senate Cutting It Close on Medicare Physician Fee Fix

Pathologists would be spared a cut and get an increase through 2008, under pending legislation. The lab bidding demo would be repealed, but lab fees would get less than the full update next year.

At press time, Senate health leaders continue talks to try to produce a Medicare spending bill before a physician fee cut of 10.6 percent takes effect July 1. Finance Committee chairman Max Baucus (D-Mont.) has also been meeting with House health leaders and says he is hopeful agreement can be reached by the deadline.

On the table in the Senate are rival Finance bills, one introduced by Baucus (S. 3101) and the other (S. 3118) by the ranking Republican Charles Grassley (Iowa). Both would offset a physician fee fix by cuts in Medicare managed care, but the Baucus bill would cut more, while Grassley's would cut less—$18 billion over five years versus $14 billion, respectively. The While House opposes any managed care cuts and said the president would veto the Baucus bill "in its current form."

In good news for pathology and clinical laboratory groups, the Baucus bill and the Grassley alternative agree on their top legislative priorities this year. These include:

- Block the July 1 physician fee cut, continue the 0.5 percent increase through Dec. 31, and grant an additional 1.1 percent increase for 2009. Congress blocked a 10 percent cut scheduled for Jan. 1, 2008 and approved a 0.5 percent fee hike for six months, through June 30.

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CMS Awards Eighth MAC Contract in Switch To New Medicare Claims Processing System

The Centers for Medicare and Medicaid Services has selected Pinnacle Business Solutions Inc. (PBSI) to handle combined Medicare Part A and Part B claims processing for clinical laboratories, pathologists, and other health care providers in Arkansas, Louisiana, and Mississippi.

This is the eighth of 15 A/B contracts that CMS will award in the nationwide transition to the Medicare Administrative Contractor (MAC) system that consolidates the workload with one entity, replacing the current system, in effect over the past 40 years, that splits the work between fiscal intermediaries for Part A and carriers for Part B.

As the A/B MAC for the tristate region (Jurisdiction 7), PBSI will take over the combined work incrementally and assume full responsibility for it no later than February 2009, CMS said in a June 11 statement. The contract has an approximate value of $178 million over five years.

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CMS Awards Eighth MAC Contract, *from p. 1*

The award to Pinnacle Business Solutions Inc. comes close on the heels of CMS's announcement last month of the seventh A/B MAC award to National Heritage Insurance Corporation to take over the claims workload for Alaska, Washington, Oregon, and Idaho (Jurisdiction 2) no later than Dec. 31 of this year (*NIR, 29, 15/May 26 '08, p. 1*).

PBSI, headquartered in Little Rock, Ark., will center the contract work there, but offices in Jackson, Miss., and in Baton Rouge and Monroe, La., will run some operations. After full implementation, approximately 300 full-time employees will be working under the contract. PBSI will subcontract with the CPA firm of Mayer Hoffman McCann P.C. to conduct SAS 70 audits of internal controls for processing and protecting transactions and data.

PBSI already is the fiscal intermediary and carrier for Arkansas and the carrier for Louisiana. In its new role as an A/B MAC, the company will also assume the claims processing functions of other fiscal intermediaries and carriers operating in the tristate region:

- Cahaba GBA, the carrier for Mississippi.
- Mutual of Omaha Insurance Company, the fiscal intermediary for some providers in Arkansas, Louisiana, and Mississippi.
- TriSpan (Blue Cross and Blue Shield of Mississippi), the fiscal intermediary for Louisiana and Mississippi.

These three states accounted for 3.7 percent of the national Medicare claims workload as of Sept. 30, 2007, CMS noted.

The contract with PBSI includes a base period, four one-year options, and award fees for meeting or exceeding performance requirements set by CMS. These include improvements in provider customer service, payment accuracy, provider education leading to correct claims submissions, and cost savings from efficiencies and innovation.

Providers, Beneficiaries Affected By Eighth MAC Contract Award

The contract to Pinnacle Business Solutions Inc. covers Arkansas, Louisiana, and Mississippi, impacting:

- 40,745 physicians and other medical professionals serving the area (as of July 31, 2007).
- 449 Medicare hospitals (as of Dec. 31, 2007).
- 1,600,092 fee-for-service beneficiaries (as of July 1, 2007).

The shift to MACs is authorized under contractor reform provisions of the Medicare Modernization Act of 2003. MAC awards are determined by open competition under federal procurement rules and must be rebid every five years. Bidders may include companies other than health insurers.

CMS says it is on track to complete the nationwide transition to 15 A/B MACs by 2009, two years ahead of schedule. In addition to the contracts to PBSI and to National Heritage Insurance Corporation noted previously, A/B MAC awards have been made for the following jurisdictions to date:

- Jurisdiction 1: California, Hawaii, Nevada, American Samoa, Guam, and the Northern Mariana Islands. The contractor is Palmetto GBA (Columbia, S.C.).
- Jurisdiction 3: Arizona, Montana, North Dakota, South Dakota, Utah, and Wyoming. The contractor is Noridian Administrative Services LLC (Fargo, N.D.).
- Jurisdiction 4: Colorado, New Mexico, Oklahoma, and Texas. The contractor is TrailBlazer Health Enterprises (Richardson, Tex.).
- Jurisdiction 5: Iowa, Kansas, Missouri, and Nebraska. The contractor is Wisconsin Physicians Health Insurance Corp. (Madison, Wis.).

- Jurisdiction 12: Delaware, Maryland, New Jersey and Pennsylvania, as well as the District of Columbia. The contractor is Highmark Medicare Services Inc. (Camp Hill, Pa.).

The transition is completed in Jurisdictions 3 and 5, while the others are at various stages of implementation, CMS said. Histocompatibility labs performing tissue typing for possible organ recipients and donors will have their claims processed by a specialty MAC yet to be selected. These labs operate on a cost reimbursement basis and bill transplant centers for their services.

Genetic Testing Is Back in the Political Spotlight

Governmental policy on genetic testing made the news again this month at both the national and the state level. On Capitol Hill, a Senate committee roundtable examined the major regulatory, scientific, and ethic issues in this fastest growing sector of the clinical laboratory industry, including direct-to-consumer (DTC) sales and marketing practices. In California, the state health department announced a new crackdown on companies that promote and sell certain DTC genetic tests online.

The Senate roundtable, convened by Gordon H. Smith (R-Ore.), the ranking member of the Special Committee on Aging, involved officials from the Centers for Medicare and Medicaid Services and the Food and Drug Administration as well as representatives from industry and academia.

The June 12 session was in follow-up to the 2006 hearing the Senator held to air complaints of exaggerated or misleading claims made in the DTC marketing of lifestyle, nutritional deficiency, and other tests. That same year, the Federal Trade Commission issued an alert advising consumers to "have a healthy dose of skepticism" about DTC genetic test claims. But even now, critics say, some companies assert their products are for screening, not diagnosis, and thus do not have to meet CLIA requirements, and they do not require a physician to order the test and do not provide pre- and post-test counseling to help interpret the findings.

Speaking on behalf of the American Clinical Laboratory Association, Elaine Lyon, Ph.D., medical director of molecular genetics at ARUP Laboratories in Salt Lake City, Utah, reiterated ACLA's longstanding concern over DTC practices and said that "for those companies that market genetic tests performed by other laboratories, any misleading claims should be investigated by the FTC." On the CLIA front, she noted, CMS has stepped up its enforcement of certification requirements for those labs that say they do not have to comply with the rules.

Lyon emphasized the value of "clinically important molecular tests in cancer diagnosis, infectious disease management like HIV, and diseases of the blood" and the need to distinguish "well established and validated tests [from] some tests being marketed directly to consumers that make unsubstantiated claims related to disease and provide advice that borders on the practice of medicine."

At-Home Genetic Tests: Let the Buyer Beware!

— No at-home genetic tests have been reviewed by the Food and Drug Administration, and the FDA has not evaluated the accuracy of their claims.

— These tests are not a suitable substitute for a traditional health care evaluation. Medical exams that include conventional laboratory tests like blood chemistry and lipid profiles are a more appropriate starting point for diagnosing diseases and assessing preventive measures.

— Because of the complexities in both the testing and the interpretation of the results, genetic tests should be performed in a specialized laboratory, and the results should be interpreted by a doctor or trained counselor who understands the value of genetic testing for a particular situation.

Source: *Facts for Consumers*, Federal Trade Commission

For example, she said, "A Web-based company offers to analyze five genes to determine insulin sensitivity. It states that loss of insulin may play an important role in common health disorders, including type 2 diabetes, high blood pressure, and heart disease. The gene testing results are provided back to the consumer, without any physician examination, glucose testing, or hemoglobin A1c testing, with suggestions for diet and lifestyle choices, including marketing of vitamins and minerals."

In California meanwhile, after an investigation of consumer complaints, the state has sent "cease-and-desist" letters to 13 companies to stop sales of DTC genetic tests to California residents. The state health department gave the companies two weeks to prove that their laboratories meet state and federal regulatory requirements and that the tests that are sold to California residents have been ordered by a physician, as state law mandates. Companies that fail to comply risk fines. The department declined to identify who got the letters until it confirmed that they had been received.

The New York State Department of Health sent similar letters to more than 20 DTC genetic test companies in April.

CMS Adds More Waived Tests to Lab Fee Schedule

Rather than wait for the next annual update of the Medicare clinical lab fee schedule, the Centers for Medicare and Medicaid Services is adding 13 more waived tests to the schedule, effective July 1 with an implementation date of July 7 (Change Request 6021).

The tests are the latest approved by the Food and Drug Administration as waived under CLIA (the Clinical Laboratory Improvement Amendments). Waived testing is the least-regulated CLIA category, requiring mainly that the user follow the manufacturer's instructions.

In billing for these tests, the CPT codes below must have the modifier QW to be recognized as waived:

CPT	*Code Descriptor*
80047QW	Basic metabolic panel (calcium, ionized)
80048QW	Basic metabolic panel (calcium, total)
80051QW	Electrolyte panel
80053QW	Comprehensive metabolic panel
82042QW	Albumin; urine or other source, quantitative, each specimen
82150QW	Amylase
82247QW	Bilirubin; total
82977QW	Glutamyltransferase, Gamma (GGT)
84075 QW	Phosphatase, alkaline
84157 QW	Protein, total, except by refractometry; other source (e.g., synovial fluid, cerebrospinal fluid)
84520 QW	Urea nitrogen; quantitative
87808 QW	Infectious agent antigen detection by immunoassay with direct optical observation; trichomonas vaginalis
87999 QW	Unlisted microbiology procedure

The number of waived tests grew from nine tests in 1993 to more than 1,600 test systems and 76 analytes in 2007, according to a recent report on the national status on laboratory medicine. The report was commissioned by the Centers for Disease Control and Prevention and released late last month (*NIR, 29, 16/Jun 9 '08, p. 1*).

♦ Medicare Claims *Advisory*

CMS Revises Policy on 'Date of Service'

The Centers for Medicare and Medicaid Services is alerting health care providers that it is revising its "date of service" (DOS) policy for tests performed on laboratory specimens and has added the technical component of physician pathology services to the policy, with an implementation date of Jan. 5, 2009 (Change Request 6018). The revisions were announced in the final Medicare physician fee schedule rule published in the November 27, 2007 *Federal Register*.

General Rule

The DOS of the test/service must be the date the specimen was collected.

Variation

If a specimen is collected over a period that spans two calendar days, the DOS must be the date the collection ended.

Exceptions

• ***DOS for tests on stored specimens***

If the specimen was stored for less than or equal to 30 calendar days from the date it was collected, the DOS of the test/service must be the date the test/service was performed only if:

—The test/service is ordered by the patient's physician at least 14 days following the patient's discharge from the hospital;

—The specimen was collected while the patient was undergoing a hospital surgical procedure;

—It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;

—The results of the test/service do not guide treatment provided during the hospital stay; and

—The test/service was reasonable and medically necessary for treatment of an illness.

If the specimen was stored for more than 30 calendar days before testing, the specimen is considered to have been archived, and the DOS of the test/service performed on it must be the date the specimen was obtained from storage.

• ***DOS for chemotherapy sensitivity tests on live tissue***

The DOS of the test/service must be the date the test/service was performed only if:

—The decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge;

—The specimen was collected while the patient was undergoing a hospital surgical procedure;

—It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;

—The results of the test/service do not guide treatment provided during the hospital stay; and

—The test/service was reasonable and medically necessary for treatment of an illness.

In applying the above exception, CMS defines a "chemotherapy sensitivity test" as "a test that requires a fresh tissue sample to test the sensitivity of tumor cells to various chemotherapeutic agents."

Medicare Physician Fee Fix, *from p. 1*

- ❑ Extend the Physician Quality Reporting Initiative through Dec. 31, 2010, while increasing the PQRI bonus to 2 percent for 2009 and 2010.
- ❑ Extend for 18 months, through 2009, the "grandfather" provision that allows independent clinical labs to bill Medicare separately for the technical component of anatomic pathology services to hospital patients. The "grandfather" protection expires June 30. Pathology and lab groups support making it permanent, while CMS has repeatedly attempted to eliminate it.
- ❑ Repeal the lab competitive bidding demonstration. The launch of the initial project in San Diego has been stopped until further notice by a preliminary injunction ordered by a federal court in a lawsuit filed against the demo by local labs and supported by national lab groups.

But along with demo repeal, both bills would reduce the CPI update to the Medicare lab fee schedule by 0.5 percent over five years. With the update for 2009 currently projected at 2 percent, this would translate to a 1.5 percent increase. The CPT lab update has been frozen at 2003 levels for the last five years, from 2004 through 2008.

In a separate provision, the Baucus bill would clarify payment for clinical lab tests furnished by critical access hospitals. These hospitals serving rural areas are to receive 101 percent of reasonable costs for clinical lab services to beneficiaries, regardless of whether the lab specimen was taken in the hospital or off-site at another facility within the county.

The Baucus bill also would give the Centers for Medicare and Medicaid Services the authority to expand the Part B preventive services benefit. This now requires congressional action. The bill would allow CMS to cover new preventive services under the Medicare National Coverage Decision process that are recommended by the U.S. Preventive Services Task Force. The House approved a similar provision last year.

The current Part B "Welcome to Medicare" preventive service visit would be modified as well by the Baucus bill. The deductible would be waived and coverage would be extended from six months to one year.

Meantime, Medicare competitive bidding is under assault on more than just clinical lab services. The other target is the nationwide rollout of bidding for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), scheduled to start July 1. Baucus and Grassley have introduced legislation to delay the implementation for 18 months, citing concerns that the project, as designed, will force many small suppliers out of the market.

HHS Eases Documentation Rules in Flood-Stricken States

HHS Secretary Michael Leavitt has declared a public health emergency in Iowa and Indiana, giving Medicare beneficiaries and their health care providers greater flexibility in meeting emergency health needs.

Because of flood damage to local health care facilities, he noted, many beneficiaries have been evacuated to neighboring communities, where receiving hospitals and nursing homes may have no health care records, information on current health status, or even verification of the person's status as a Medicare beneficiary. The Centers for Medicare and Medicaid Services is assuring these facilities that, in this circumstance, the normal burden of documentation will be waived and they can act under a presumption of eligibility.

Call for Nominations
2008 Laboratory Public Service National Leadership Award

You are invited to submit your nomination of an individual to receive this annual award presented by Washington G-2 Reports/IOMA to recognize a significant contribution to the public interest through accomplishments that directly enhance patient care and the laboratory profession.

Nomination Deadline

All nomination forms must arrive no later than July 31, 2008 at Lab Award, Attn: Perry Patterson, Washington G-2 Reports, 1 Washington Park, Newark, NJ 07102. Forms may also be faxed to 973-622-0595. An independent board of industry representatives will consider all nominations and select the recipient of the award.

Award Presentation

This 2008 award, sponsored by Kellison & Co., will be presented during Lab Institute 2008, Sept. 17-19, at the Crystal Gateway Marriott Hotel in Arlington, Va. (adjacent to Reagan National Airport).

Award Criteria

The Laboratory Public Service National Leadership Award is bestowed for accomplishments in one or more of the following areas:

- Advancing the profession
- Basic or applied research
- Business creativity and innovations
- Public policy
- Lifetime achievement
- Performance of a special service, task, or project benefiting the laboratory community

Award Recipients To Date

1993 Shirley Ann Pohl, posthumous (lifetime achievement in advancing clinical laboratory science and the education and training of medical technologists)
1994 Helen and Alfred Free (lifetime achievements in scientific and professional advances, pioneers in dipstick urinalysis)
1995 Elizabeth Dragon, Ph.D. (basic/applied research)
1996 Senator William Cohen, chief sponsor of the CLIA statute (public policy)
1997 William H. Hamlin, M.D. (professional achievement)
1998 John Bernard Henry, M.D. (professional achievement)
1999 Harvey J. Alter, M.D. (lifetime achievements in laboratory science and public health)
2000 Elissa Passiment, executive vice president, American Society for Clinical Laboratory Science (professional achievement)
2001 J. Stephen Kroger, M.D., F.A.C.P. (professional achievement)
2002 John M. Matsen, M.D. (lifetime achievement)
2003 Arthur Karmen, M.D. (lifetime achievement)
2004 James O. Westgard, Ph.D. (lifetime achievement)
2005 Joan Logue, coding expert (lifetime achievement)
2006 Michael Laposata, M.D., Ph.D. (lifetime achievement)
2007 Dennis Weissman (education/training programs)

Customized E-Links Between Hospital, Doctors Okay Under Stark

A hospital system's plan to develop and provide customized interfaces between its electronic health records system and those owned by staff physicians and used in their offices would not constitute a compensation arrangement subject to the Stark physician self-referral restrictions, the Centers for Medicare and Medicaid Services said in an advisory opinion issued this month (No. CMS-AO-2008-01). Thus, the hospital can proceed without having to satisfy a related Stark law exception, the agency found.

In the particulars of the case, the hospital said it would contract with a software vendor to develop the interfaces. The hospital has proprietary software that allows its staff physicians to view patient data and to order clinical laboratory tests and communicate test results. The physicians also can examine lab reports over a protected Internet connection to the hospital's e-health records system.

The hospital now wants the physicians to have broader access to patient data and the ability to order lab tests from their office practices, a move that would require integrating the hospital's in-house system with differing e-health record systems among the practices. The interfaces would be used solely for ordering and communicating lab tests and procedures furnished by the hospital.

Lab Institute 2008 Alert!

Join us for our 26th annual Lab Institute, Sept. 17-19 at the Crystal Gateway Marriott Hotel in Arlington, Va. (adjacent to Reagan National Airport).

This is the premier event for the lab and pathology industry, your early-warning venue for objective, accurate information and forecasts on legislative, policy, business, and technological challenges impacting your 'bottom-line.'

This year's program, *The Changing of the Guard*, examines fundamental realignments in politics, Medicare and health care reform policy, personalized medicine, and the molecular diagnostics market. Also, choose from a host of workshops on successful business and financial models, including entrepreneurial pathology, blood utilization control, and much more. Also, check out our special all-day Lab Leaders' Bootcamp for lab managers.

To register or get program details, go to *www.g2reports.com/labinstitute08*.

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