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House Leaders Call For Halt To Medicare Lab Bidding Demo

Meantime, CMS officials have announced a tentative timeline for the demo, with the launch planned for the spring of 2008.

Sustained lobbying by clinical laboratory and pathology groups against the Medicare competitive bidding demonstration for clinical lab services paid off in the House early this month as Congress went on recess until after Labor Day.

On August 4, Nydia Velazquez (D-NY), chairwoman of the House Committee on Small Business, introduced legislation (H.R. 3453) that would repeal the statutory provision (in the Medicare Modernization Act of 2003) that requires the Centers for Medicare & Medicaid Services to implement a lab bidding demo.

Further, the bill would require that CMS report to House and Senate small business committees about the impact of competitive bidding on small clinical labs.

On August 7, John Dingell (D-MI), chairman of the House Energy & Commerce Committee, asked Health & Human Services Secretary Michael Leavitt to respond to a series of demo-specific questions by no later than August 20. "In applying competitive bidding to something as complex as lab services," Dingell wrote, "care must be taken that, even in demonstration, the concept neither compromises the availability of quality lab services to beneficiaries nor adversely affects small labs serving vulnerable Medicare populations." *Continued on p. 2*

INSIDE *NIR*

Next Stop For Physician Fee Fix: House-Senate Conference Action

Under legislation that passed the House August 1, pathologists and other physicians would be spared the scheduled 10% cut in Medicare fees in 2008 and would be guaranteed at least a 0.5% update next year and in 2009. The cost over five years would be an estimated $20 billion.

The bill would replace the current SGR (sustainable growth rate) formula used to calculate annual physician fee updates with a new system of expenditure targets for six categories of physician services.

Further, the bill would overhaul the Part B preventive services package by eliminating beneficiary cost-sharing and by giving the Centers for Medicare & Medicaid Services the authority to act on its own, without waiting for Congress, in adding to or otherwise changing the benefit.

The physician fee increase and the preventive services overhaul are part of the House measure reauthorizing *Continued on p. 5*

Nearly 5,000 independent clinical labs are classified as small business entities by the Small Business Administration, and most receive 40% of their revenue from Medicare, according to findings included in the bidding demo repeal bill, H.R. 3453.

Medicare Lab Bidding Demo, *from p. 1*
Velazquez introduced H.R. 3453, titled the "Community Clinical Laboratory Fairness in Competition Act of 2007," in the wake of the July 25 hearing she convened to air lab industry concerns about the project's impact on small and medium-size local labs and on special beneficiary groups, such as nursing home and homebound patients (*NIR, 28, 19/Jul 30 '07, pp. 1, 4-6*).

Praising Velazquez for sponsoring the bill, Mark Birenbaum, administrator of the American Association for Bioanalysts and the National Independent Laboratory Association, cautioned that "this is a first step" and a lot more must be done to get it passed. "Our effort in the months ahead will be to get additional co-sponsors and a Senate companion bill," he told the *National Intelligence Report*.

Alan Mertz, president of the American Clinical Laboratory Association, agreed, telling *NIR* that the industry's legislative strategy "hasn't changed, but it has got momentum." The most promising avenue at present for passage of H.R. 3453, he noted, is to get it attached to the reauthorization legislation for SCHIP (State Children's Health Insurance Program), now awaiting House-Senate conference action. It's likely to be the only major healthcare bill to move this year, he said.

Birenbaum told *NIR* he hopes CMS will take note of the growing congressional involvement with demo issues. Given the sympathetic ear the demo's opponents have been getting on Capitol Hill, he said CMS might well ponder whether moving forward with the project is the wisest way to proceed.

Regardless, Birenbaum said, CMS officials still have to address many questions raised by the lab industry. One key issue is the requirement that all labs in the competitive bid area with $100,000 or more in annual revenue from demo tests must bid or risk being shut out of Medicare lab payments for the three-year run of the project. Labs below the revenue threshold are "passive" labs and don't have to bid, but will be paid at the competitively set rate.

The revenue threshold in the demo is only 2% of the Small Business Administration's definition for small labs ($12.5 million or less in overall business), the Clinical Laboratory Coalition has noted to CMS. Is it realistic, the coalition asked, to expect that small local labs will be in a position to compete with the large national labs in the demo?

And how could this jeopardize services to the most vulnerable beneficiaries? Dingell raised this question in his letter to Leavitt: "What steps have been taken to ensure that the demo includes winning labs that will guarantee quality services to nursing home and homebound patients? Or if none of the local labs serving [them] are winners, how will CMS ensure that these populations have access to needed services? And how will the level of service be identified to bidders in advance so they can reflect those costs in their bid prices?"

Dingell also asked why CMS is requiring "niche" labs that offer only a few tests to bid on the full range of demo tests. "If these labs are not selected, they will be precluded from providing their specialized test services throughout the life of the demo," he noted. "How will CMS guarantee capacity and access to this subset of unique tests if these labs are not winning bidders?"

The purpose of the demo is to see if competitive bidding can be used to pay for Part B lab services at rates below the current fee schedule. The project would:

- ❑ Run for three years in two Metropolitan Statistical Areas within a single state.
- ❑ Include independent lab services. Exclude tests by physician office labs (POLs) and by hospitals for their patients. Would include outreach and/or non-patient services provided by a hospital or a POL where the lab is functioning, in effect, as an independent lab.
- ❑ Cover 358 "demo tests" that correspond to 99% of the fee schedule by national volume and total payment.
- ❑ Exclude Pap smears, colorectal cancer screening, and tests added to the fee schedule during the project's three-year run, and rely on CLIA standards to assure quality.
- ❑ Mandate that bid prices be provided for all demo tests, whether done in-house or sent to reference labs.

'Pod' Labs: No Summary Execution, Just Slow Strangulation

In the physician fee schedule proposal for 2008, the Centers for Medicare & Medicaid Services proposed significant changes to the purchased diagnostic test rules and the Stark physician self-referral rules. The comment period closes at the end of this month, and a final rule is expected in late fall.

'Pod' Lab Curbs

While CMS declined to slap an outright ban on controversial pod lab arrangements, it has proposed changes that would restrict their profitability. Clinical laboratory and pathology groups have long lobbied against pod labs, saying they enable certain physician specialty groups to exploit Medicare loopholes and capture increased Medicare revenue from pathology referrals.

CMS would expand the purchased diagnostic test rules so that the anti-markup provisions apply to both the professional and the technical components (the PC and the TC) billed by a physician or medical group, but performed by someone other than a full-time employee. The provisions would not apply to independent labs that have not ordered the TC. The proposed changes have the backing of the College of American Pathologists and the American Clinical Laboratory Association.

The anti-markup provisions would apply regardless of whether the billing physician purchases the component or the right to payment for the component is reassigned to the billing physician. To prevent gaming, the performing physician's or other supplier's "net charge" would be defined as exclusive of any amount that takes into consideration the cost of equipment or space leased to the performing physician or other supplier.

The practical effect is that CMS would economically eliminate pod labs, attorney Robert Mazer, a shareholder with Ober/Kaler (Baltimore, MD), told the *National Intelligence Report*. Industry sources also note that increasing legal risks continue to fuel the trend among physician specialties to move away from pod labs toward establishing in-house labs for their pathology work.

'Set In Advance' Standard

Labs and physicians should also take note, Mazer told *NIR*, that under CMS' proposed changes, percentage-based compensation generally would not be considered "set in advance," which is one of the requirements in the Stark exceptions for space and equipment leases, personal service arrangements, and fair market value compensation.

Similarly, the exceptions for lease of office space and equipment would no longer protect any arrangement, Mazer said, where payments were made on a per unit-of-service (per-click) basis. However, these exceptions generally apply only when there is a direct contract between a physician and a provider of designated health services (DSH), such as a hospital or a lab.

When the DSH provider contracts with a group practice or other legal entity that has a financial relationship with the physician, any relationship between the DSH provider and the physician is an indirect compensation arrangement, Mazer noted. The particular exception for such arrangements that would potentially apply does not have a "set in advance" requirement. Therefore, the proposed change may not impact indirect financial relationships.

However, Mazer cautioned, "CMS has indicated that 'commenters should be mindful that we [sic] finalize (or may have already finalized) a provision that treats physicians as standing on [sic] the shoes of their group practices or other physician practices.' If that were to occur," the DSH provider's contract arrangement with the group practice would be deemed to result in a direct financial relationship between the DSH provider and the physician. Then the exceptions affected by the changes could become applicable and have a much broader impact."

Change Proposed In Lab Fee-Setting Process

Attorney Peter Kazon, senior counsel with Alston & Bird in Washington, DC, told *NIR* that labs should be alert to a change in the physician fee schedule proposal that would affect the public process CMS now follows annually to obtain public input to help establish fees for new codes on the Part B lab fee schedule. After getting input and responding, the agency makes a final fee decision for a new test, and that's the end of it.

Now, CMS is proposing to create a process for reconsideration of that decision if a provider disagrees with the method used—crosswalk or gap-fill—to set a Medicare payment rate.

Lab-Developed Tests: Which Are Subject To FDA Review?

The revised guidance is posted at www.fda.gov/cdrh/oivd/guidance/1610.pdf.

That's an issue the Food & Drug Administration seeks to clarify in its revised draft guidance, issued July 26, spelling out how the agency will handle newly required premarket review of certain lab-developed tests (LDTs). Comments are due August 27.

The types of LDTs under FDA scrutiny include a category called "in vitro multivariate index assays" (IVDMIAs). They combine an assay(s) with an algorithm (typically proprietary) to generate a patient-specific result. Tests like these are used in genetic testing for disease or the risk of it. The FDA thinks more oversight is needed because the proprietary formulas make it hard for physicians to independently determine the tests' clinical validity (*NIR, 28, 19/Jul 30 '07, p. 8*).

The FDA said commenters on the initial draft guidance issued last September misconstrued the scope of LDTs for which premarket review would be required as class II or III devices (*NIR, 28, 9/Feb 26 '07, p. 1*). To address this, the revised guidance provides examples, real or hypothetical, of devices that would be an IVDMIA:

- Gene expression profiling assay for breast cancer prognosis.
- A device that integrates quantitative results from multiple immunoassays to obtain a qualitative "score" that predicts a person's risk of developing a disease or condition.

- A device that integrates a patient's age, sex, and genotype of multiple genes to predict risk of or diagnose a disease or condition.

The FDA would *not* consider as IVDMIAs those devices with a function that simply facilitates interpretation of multiple variables that healthcare practitioners could otherwise interpret themselves. For example:

- Standard maternal Triple Screen testing—measurement in the second trimester of AFP, hCG, and estriol.
- Genotype determination such as CFTR genotyping.
- Chromosomal copy number determination.
- Common clinical calculations such as creatinine clearance, determination of cholesterol ratios, and estimated glomerular filtration rate.
- Devices such as Clinical Decision Support tools that analyze stored clinical information to, for example, flag patient results based on specific clinical parameters (e.g., out of range results, potential drug interactions, opportunities for complementary tests, etc.), create disease registries, summarize patient-specific information in an integrated report, and/or track a patient's treatment or disease outcome.
- Common, public demographic risk calculations (e.g., Gail Index, Framingham Risk Score).

Physician Fee Fix, *from p. 1*

the State Children's Health Insurance Program (SCHIP). However, the version of SCHIP reauthorization that passed the Senate August 2 includes no Medicare provisions.

SCHIP is the popular program that states increasingly are relying on to expand healthcare coverage to children in families that make too much to qualify for Medicaid but not enough to afford private insurance. It expires September 30.

The House-Senate conference committee will have to grapple with key differences over how to expand SCHIP and pay for it. The House bill would authorize $50 billion over five years, paying for it with higher tobacco taxes and reduced Medicare managed care payments. The Senate bill would authorize $35 billion over five years, paying for it by raising the tobacco tax.

Health insurers have strongly objected to provisions that would level Medicare managed care payments to 100% of traditional Part B fee-for-service. The Medicare Payment Advisory Committee has concluded that Medicare Advantage plans get 12% higher pay rates on average than traditional Medicare, but health plan groups dispute this, denying their rates are an overpayment.

Conferees on SCHIP will also be weighing the President's veto threat. Mr. Bush has proposed reauthorizing SCHIP at $5 billion over five years. He would fix the eligibility threshold at 200% of the federal poverty level. Many states have a higher threshold, as much as 300% to 400%. The President favors tax credits to encourage private insurers to offer affordable coverage to low-income families above 200%. The federal share of SCHIP funding is 70%, with the rest supplied by the states.

Extension Of Pathology 'Grandfather' Protection

The Medicare changes in the House-passed SCHIP bill include a provision to extend for two years, through 2009, the pathology "grandfather" protection that allows independent labs to bill Medicare for the technical component of services to hospital inpatients and outpatients. The protection is set to expire at the end of this year, and the Centers for Medicare & Medicaid Services is again proposing to eliminate it.

CMS contends the TC is reimbursed in the hospital's prospective payment, and the lab should seek payment from the hospital, not Part B.

The protection applies to hospital-lab arrangements in effect as of July 22, 1999 (the date CMS first proposed to end the TC billings).

♦ MEDICARE CODING *Advisory*

Practical Implications Of The New 2008 Lab Codes

Charles Root, PhD, president, CodeMap

Editor's Note: *Medicare Part B will add seven new CPT 2008 codes to the lab fee schedule and is proposing a new HCPCS code for diabetes testing, effective January 1. Fee-setting recommendations for crosswalking the codes to existing CPT codes have been submitted by laboratory and pathology groups (NIR, 28, 19/Jul 30 '07, p. 3). Below is an analysis of what the coding additions mean to the lab industry and to clinical practice. CPT codes © American Medical Assn.*

Organ/Disease Panels

80047 - Basic metabolic panel (Calcium, ionized)

The existing basic metabolic panel (BMP) includes eight common serum blood chemistries used in diagnosing a wide variety of disorders. Many point-of-care test panels for metabolic function typically include ionized calcium rather than total calcium and consequently cannot be reported using the existing BMP code. The new code for BMP (Calcium, ionized) allows point-of-care basic metabolic panels to be reported using a single code rather than eight individual codes as presently required by coding rules. The existing Basic Metabolic Panel code (80048) will remain in the CPT and be revised to read "Basic metabolic panel (Calcium, total)."

Chemistry

82610 - Cystatin C

Cystatin C is a cysteine proteinase inhibitor produced by all nucleated cells. Since its serum concentration is inversely correlated with the glomerular filtration rate (GFR), Cystatin C levels are used in the diagnosis and treatment of renal diseases. Since the serum concentration of Cystatin C remains unchanged with infections, inflammatory or neoplastic states, and is not affected by body mass, diet, or drugs, it is useful as an index of GFR, especially in obese, elderly, and malnourished patients. The test is currently available on automated chemistry systems and is considered by many to be a better test for renal function than creatinine clearance.

82610 - Calprotectin

Calprotectin is a calcium-binding protein secreted predominantly by neutrophils. Elevated fecal calprotectin levels have been observed in patients with inflammatory bowel disease (IBD) and GI tract infections. Elevated levels often precede clinical relapse in patients with quiescent IBD. Fecal calprotectin is also elevated in patients with non-steroidal anti-inflammatory drug (NSAID)-induced enteropathy. The test promises to be useful in the diagnosis and treatment of a wide range of GI diseases.

84704 - Gonadotropin, chorinoic (hCG); free beta chain

Measurement of free Beta hCG is recommended in screening for Down syndrome in the first trimester of pregnancy. The effectiveness of free Beta as an important discriminatory marker for Down syndrome in the first trimester has been proven in two trials sponsored by the National Institutes of Health and 20 worldwide published studies. Currently in the U.S., the vast majority of free Beta analyses are performed on dried blood spot specimens because the ease of collection and transport increases the availability of the test. Moreover, the inherent stability of the specimen leads to greater discrimination between normal and affected cases.

Immunology

86356 - Mononuclear cell antigen, quantitative, (eg, flow cytometry), not otherwise specified, each antigen

This code describes otherwise unlisted cell surface markers typically determined by flow cytometry. Such markers are frequently used in the diagnosis and treatment of leukemia and other hematological disorders.

Microbiology

87500 - Vancomycin resistance (eg, enterococcus species van A, van B), amplified probe technique

Acquired microbial resistance to vancomycin is a growing problem within healthcare facilities such as hospitals and nursing homes. Vancomycin-resistant enterococci (VRE) emerged in 1987 and Vancomycin resistance in more common pathogenic organisms appeared during the 1990s and 2000s, including vancomycin-intermediate Staphylococcus aureus (VISA), vancomycin-resistant Staphylococcus aureus (VRSA), and vancomycin-resistant Clostridium difficile. Diseases associated with VRE include Urinary Tract Infections (UTI), wound infections, endocarditis, bacteremia, and meningitis. This code will be used to report Vancomycin resistance to any infectious agent using DNA or RNA-based amplified probe techniques.

87809 - Infectious agent antigen detection by immunoassay with direct optical observation; Adenovirus

Human adenoviruses (HAdVs) are one of the most commonly isolated viruses and are a significant cause of diseases of the respiratory tract and eye. Pharyngoconjunctival fever (PCF) is a widely known adenoviral disease. HAdVs, particularly types 7 and 3, are also known to cause pneumonia. Furthermore, HAdVs are increasingly being recognized as fatal pathogens in immunocompromised patients. This new code will allow the reporting of HadV detection using point-of-care devices.

New HCPCS Code

Gxxxx - Hemoglobin; glycosylated (A1c)

A1c, also known as glycated hemoglobin or glycosylated hemoglobin, indicates a diabetic patient's blood sugar control over the last two to three months. A1c values are directly proportional to the concentration of glucose in the blood over the full life span of the red blood cells and are not subject to the fluctuations that are seen with daily blood glucose monitoring. As such, the monitoring of A1c in diabetic patients is an important factor in controlling their blood sugar levels and preventing complications.

A new code for point-of-care A1c tests (83037) was published in the 2006 CPT and is currently reimbursed at $21.06. Laboratories using other analysis techniques must report A1c using CPT code 83036 which pays only $13.56.

The proposed HCPCS code, if established by CMS, would result in a single code and payment for A1c tests paid from the Medicare Laboratory Fee Schedule. However, both of the existing CPT codes (83036 and 83037) could be used to submit claims to non-government payers.

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For the Record

In the July 30 issue (p. 3), we summarized the fee recommendations of lab and pathology groups for codes new to the Medicare lab fee schedule in 2008. The list of those objecting to CMS's proposed "G" code for hemoglobin A1c testing as not necessary should have included the American Clinical Laboratory Association, along with the College of American Pathologists, the American Society for Clinical Pathology, and the Clinical Laboratory Management Association.

NPI Provider Data Release Delayed Until September

The data release is aimed at helping providers and their trading partners exchange NPIs and use them in standard electronic transactions, as required by HIPAA (the Health Insurance Portability & Accountability Act).

The Centers for Medicare & Medicaid Services has postponed release of National Provider Identifiers (NPIs) and other provider data from the National Plan & Provider Enumeration System (NPPES) until September 4. The agency had previously set the first of August as the target date (*NIR, 28, 19/Jul 30 '07, p. 7*).

CMS says it is granting more time so healthcare providers can check the accuracy of the information culled from their NPI application, update it where necessary, and resolve potential problems prior to initial release. NPPES data will be available in two forms: a query-only database, known as the NPI Registry, and a downloadable file. While the registry will open September 4, the downloadable file will be ready approximately one week later. CMS has already identified what data will and will not be disclosed (*NIR, 28, 16/Jun 11 '07, p. 5*).

To ensure that edits are reflected in the NPI Registry when it first becomes operational and in the first downloadable file, providers must submit their edits no later than August 20. Those submitting edits on paper must mail them in time for receipt by that date. For details, go to the NPI Web page, *www.cms.hhs.gov/NationalProvIdentStand/*.

Reminder: August is a one-issue month for *NIR*.

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