WASHINGTON G–2 REPORTS

NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 30th Year of Publication

Vol. 09, Iss. 9, May 11, 2009

Congress Eyes Two-Year Medicare Physician Fee Fix

Pathology and other groups want to ax the current Medicare fee update formula in favor of one that assures "reasonable and constant" updates, note industry sources. The short-term fix, while not ideal, would stabilize the situation for a while until a fundamental correction to the fee system can be enacted.

In the opening round of legislative action on health care reform, Congress has signaled that a complete overhaul of the Medicare physician payment system could be put off for at least two more years. For the present, lawmakers envision blocking the physician fee cut of 21 percent scheduled for 2010, granting a two-year payment increase, and letting the committees of jurisdiction decide how to pay for it.

Provisions for a two-year physician fee fix were approved in the final budget resolution for fiscal 2010 that passed the House by a vote of 233-193 and the Senate by a vote of 53-43 on April 29, with no Republicans in either chamber voting for it. While the budget resolution is largely nonbinding and does not require the president's signature, it is a blueprint of the revenue and spending priorities of the majority party.

The final budget plan approves establishment of the reserve fund requested by President Barack Obama to help finance health care reform initiatives. The president requested $634 billion for the fund as a "down payment" on reform, including $330 billion that could be tapped to revamp Medicare physician payments. *Continued on p. 2*

What's at Stake for Labs in Proposed Public Plan Option?

Among the legislative proposals to expand health care coverage to millions of uninsured Americans, one of the most controversial is the creation of a government-run public plan that would compete with private health insurers. Democrats generally favor it, while Republicans and insurers oppose it as unfair market competition.

For the clinical laboratory industry, the public plan option raises several major concerns, said Diane DeGette (D-Colo.), deputy House majority whip, during a May 6 session of the annual conference of the American Clinical Laboratory Association (ACLA) in Washington, D.C.

How this new option would shape and finance the benefit package is an area where labs need to get involved, she said. The major issues are coverage of lab services as a basic benefit, no copay for prevention and wellness services, and adequate reimbursement for lab services.

Of some 47 million uninsured Americans, an estimated 20 million to 35 million could enroll in the public plan, some analysts project, giving the government more market muscle to decide trends in benefits and how much to pay for them. *Continued on p. 2*

INSIDE *NIR*

www.g2reports.com

Congress Eyes Two-Year Medicare Physician Fee Fix, *from p. 1*

In the Senate, two options for increasing Medicare physician fees have been floated by Finance committee chairman Max Baucus (D-Mont.) and ranking Republican Charles Grassley (Iowa) in a discussion paper released April 28. One option would be "to update the Part B fee schedule by one percentage point in 2010 and 2011 and freeze it in 2012. Calculations under the current sustainable growth rate (SGR) formula to determine updates would then revert to the current law for 2013."

Another option would "have the same schedule of updates for 2010-2012 as in the above option; however, once the update calculation reverted to current law SGR for 2012, a floor of minus 3 percent would be in effect. Beginning in 2014, the fee schedule update for localities with two-year average fee-for-service growth rates at or greater than 110 percent of the national average would have a minus 6 percent floor."

In agreeing to the final budget, the House punted to the Senate to come up with ways to pay for the increase, potentially with payments cuts from other Medicare providers. But the budget's most controversial component is approval of use of the reconciliation process after Oct. 15 if health care reform legislation has stalled. Under this process, the legislation requires only 51 votes to pass in the Senate and prevents having to muster 60 votes to overcome a filibuster. Senate Republicans have objected that resorting to reconciliation would doom any bipartisan effort. Democrats say they want to work with Republicans to pass health care reform, but the GOP should not be able to block action.

What's at Stake for Labs in Proposed Public Plan Option?, *from p. 1*

In addressing how the health care reform debate is shaping up, DeGette, who is vice chair of the House Energy and Commerce committee, said there is agreement on broad principles as various congressional panels begin work on health care reform legislative initiatives. The aim must be health care coverage that is universal, portable, and affordable, she emphasized. Reform will work within current and new structures. A single-payer system is regarded as not realistic and off the table, she said. In addition to the public plan option, another flashpoint for controversy is whether to mandate that individuals obtain health care coverage in either public or private plans.

Norman Ornstein, veteran political analyst and resident scholar at the American Enterprise Institute, told the ACLA audience that he sees a 50 percent chance that Congress will enact health care reform legislation this year, though it likely will not be comprehensive. Democrats want to go into next year's midterm congressional elections citing progress in expanding coverage and lowering costs. And the prospect of using reconciliation to enact some health care reforms gives Democrats leverage to bring Republicans to the table if they want to have a say in the matter. Chances for reform are also brighter because the various interest groups back major action and the number of uninsured keeps rising as the economic recession plays out.

On the genetic testing front, more regulation is in the offing, Food and Drug Administration official Alberto Gutierrez said at the ACLA meeting. Gutierrez, who is in charge of new device evaluation, said maintaining different standards for in vitro diagnostics and lab-developed tests (LDTs) is becoming less tenable. The FDA also is concerned that some companies may be setting up facilities to offer tests as LDTs, thus avoiding premarket review requirements.

Labs to HHS Secretary: Strike 'Regulatory Balance' on Genetic Tests

Ten national clinical laboratory and pathology organizations are urging Health and Human Services secretary Kathleen Sebelius to take the leadership in having her department advance personalized medicine by striking a balance in regulation of genetic and molecular testing.

In an April 29 letter, the groups said, "Genetic testing currently accounts for a relatively small but rapidly growing proportion of aggregate health care expenditures. However, it forms the cornerstone of personalized medicine, delivering the right drug to the right patient at the right time. Consequently, it is vital for us to maintain a regulatory environment that will foster and encourage development of this nascent field, delivering important benefits to patients, while protecting the public from unnecessary risks of harm."

Sebelius Takes the Helm at HHS

Kansas Democratic Gov. Kathleen Sebelius joined President Barack Obama's cabinet as secretary of Health and Human Services in a swearing-in ceremony on April 28, following her confirmation by the Senate earlier that day.

She received a friendly reception at her confirmation hearing before the Finance committee, but later ran into objections raised by some Republicans to her positions on abortion and comparative effectiveness. But Finance approved her nomination April 21 by a vote of 15 to 8, and the full Senate endorsed it on April 28 by a margin of 65 to 31.

Supporters say her tenure as Kansas governor and state insurance commissioner, along with her ability to work with Republicans in that state, make her uniquely qualified to serve as HHS secretary and take the lead in working for bipartisan health care reform measures.

The groups advocate a regulatory model that they say will allow genetic and molecular testing to "fulfill its potential for patient care and health care cost savings" and request a meeting with Sebelius to discuss it. As outlined in the letter, the model would:

- Improve the interagency coordination between the Centers for Medicare and Medicaid Services and the Food and Drug Administration.
- Utilize the Clinical Laboratory Improvement Amendments to regulate clinical laboratory testing services, in particular lab-developed tests (LDTs).
- Avoid overlapping and potentially conflicting regulatory requirements that impede innovation.
- Provide a publicly transparent genomic test registry.
- Allow for a participatory approach that draws on the expertise of all industry stakeholders.

Signing the letter were the following organizations:

- American Association of BioAnalysts
- American Association for Clinical Chemistry
- American Clinical Laboratory Association
- American Medical Technologists
- American Society for Clinical Pathology
- American Society for Clinical Laboratory Science
- American Society for Microbiology
- Clinical Laboratory Management Association
- College of American Pathologists
- National Independent Laboratory Association

focus on: The H1N1 Flu Outbreak

Labs on the Front Line in Swine Flu H1N1 Pandemic

Information and guidelines, including those on H1N1 laboratory testing, may change as more is learned about this disease. Current information, including case definitions and infection control guidelines, is available at http://www.cdc.gov/swineflu.

The outbreak of swine influenza A (H1N1) viral infection in humans is the latest case study of where clinical laboratories in all settings and all countries need to be in a global public health emergency. Labs in this country and worldwide have been essential in detecting, tracking, and guiding treatment, underscoring how indispensable lab linkages are in responding rapidly to new and novel viruses and other emerging disease threats.

Lab discoveries have been vital in helping hospitals that see patients with suspected cases of H1N1 infection, independent labs that get physician office referrals of suspected cases, and researchers who are studying the origins and mutations of the virus.

In the United States, federal agencies, the Association of Public Health Laboratories, and other groups have moved swiftly in response to the public health emergency declared April 26 by the U.S. Department of Health and Human Services (HHS), following confirmed cases of H1N1 in California, Texas, Kansas, and New York. Here is a rundown of special lab alerts at press time on biosafety, emergency use of a test panel, and how to perform H1N1 testing.

Biosafety Guidelines for Lab Personnel

The Centers for Disease Control and Prevention (CDC) has issued biosafety guidelines for laboratory personnel who may be processing or performing diagnostic testing on clinical specimens from patients with suspected H1N1 infection or who are performing viral isolation.

Diagnostic lab work on clinical samples from patients who are suspected cases should be conducted in a BSL2 lab. All sample manipulations should be done inside a biosafety cabinet (BSC). Viral isolation on clinical specimens from suspected cases should be performed in a BSL2 lab with BSL3 practices (enhanced BSL2 conditions).

Additional precautions include personal protective equipment (based on site-specific risk assessment), respiratory protection (fit-tested N95 respirator or higher level of protection), shoe covers, closed-front gown, double gloves, and eye protection (goggles or face shields). All waste disposal procedures should be followed as outlined in the lab's standard operating procedures, including appropriate disinfectants, 70 percent ethanol, 5 percent Lysol, and 10 percent bleach.

All personnel should monitor themselves for fever and symptoms such as cough, sore throat, vomiting, diarrhea, headache, runny nose, and muscle aches. Any illness should be reported to the lab worker's supervisor immediately. For personnel who had unprotected exposure or a known breach in personal protective equipment to clinical material or live virus from a confirmed case of H1N1, antiviral chemoprophylaxis with zanamivir or oseltamivir for seven days after exposure can be considered. For additional information, see *Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition* Section IV Laboratory Biosafety Level Criteria at www.cdc.gov.

Emergency Use of Test Panel

The Food and Drug Administration on April 28 gave the green light to public health and other qualified laboratories to make emergency use of the Swine Influenza Virus Real-Time RT-PCR Detection Panel (rRT-PCR Swine Flu Panel) for the presumptive diagnosis of H1N1 infection. The authorization terminates on April 26, 2010 or when the emergency has ceased to exist, whichever is earlier.

At this time, no FDA-approved or-cleared tests that identify the existence of H1N1 virus in clinical specimens are available in this country, the agency said. Therefore, the CDC developed the test panel to detect the virus. The test panel is authorized for use in "individuals who have been diagnosed with influenza A caused by a virus not subtypeable by currently available FDA-cleared devices."

The CDC is distributing the rRT-PCR Swine Flu Panel labeled with the intended use, adequate directions for use, any appropriate limitations on use of the device, and any available information regarding performance of the device. The agency also provides flu panel fact sheets for health care providers and patients.

The authorized rRT-PCR Swine Flu Panel is a panel of oligonucleotide primers and dual-labeled hydrolysis (Taqman®) probes for use in the real-time RT-PCR assay on the ABI 7500 Fast Dx Real-Time PCR instrument for the in vitro qualitative detection of swine influenza viral RNA in nasopharyngeal and/or nasal swab specimens from patients with signs and symptoms of respiratory infection and viral culture. The universal swine influenza swInfA (NP gene) and swH1 (HA gene) primer and probe sets are designed for detection of swine A/H1N1 influenza viruses.

The assay is to be performed on an Applied Biosystems 7500 Fast Dx Real-Time PCR instrument or the RUO-marketed Applied Biosystems 7500 Real-Time PCR instrument that is validated by Applied Biosystems with regard to the updated software but only partially qualified regarding its lab performance (proficiency testing with the CDC sample panel not performed).

Qualified laboratories must have a process in place for reporting test results to health care providers and federal, state, or local public health authorities, and the CDC will track adverse events.

Guidance on H1N1 Testing

The CDC on April 30 issued interim guidance to laboratories on specimen collection, processing, and testing for patients with suspected H1N1 virus infection.

Case Definitions

A *confirmed* case of H1N1 infection is defined as a person with an acute febrile respiratory illness with laboratory-confirmed H1N1 virus infection by one or more of the following tests:

1. real-time RT-PCR
2. viral culture

A *probable* case is defined as a person with an acute febrile respiratory illness who is:

- ❑ positive for influenza A, but negative for H1 and H3 by influenza RT-PCR, or
- ❑ positive for influenza A by an influenza rapid test or an influenza immunofluorescence assay (IFA), plus meets criteria for a suspected case.

A *suspected* case is defined as a person with acute febrile respiratory illness with onset:

- ❑ within seven days of close contact with a person who is a confirmed case of swine influenza A (H1N1) virus infection, or
- ❑ within seven days of travel to a community either within the United States or internationally where there are one or more confirmed swine influenza A(H1N1) cases, or
- ❑ resides in a community where there are one or more confirmed swine influenza cases.

Duration of Viral Shedding

The duration of shedding with H1N1 is unknown. Therefore, until data are available, the estimated duration is based on seasonal influenza virus infection. Infected persons are assumed to be shedding virus and potentially infectious from the day prior to illness onset until resolution of fever. Infected persons should be assumed to be contagious up to seven days from illness onset. Some persons who are infected might potentially shed virus and be contagious for longer periods (e.g., young infants, immunosuppressed and immunocompromised persons).

Testing for H1N1

Clinicians should consider testing suspected cases by obtaining an upper respiratory specimen. Preferred specimens to be collected as soon as possible after illness onset include nasopharyngeal swab/aspirate or nasal wash/aspirate. If these cannot be collected, a combined nasal swab with an oropharyngeal swab is acceptable. For patients who are intubated, an endotracheal aspirate should also be collected. Specimens should be placed into sterile viral transport media (VTM) and immediately placed on ice or cold packs or at 4°C (refrigerator) for transport to the lab.

Ideally, swab specimens should be collected using swabs with a synthetic tip (e.g., polyester or Dacron®) and an aluminum or plastic shaft. Swabs with cotton tips and wooden shafts are not recommended. Specimens collected with swabs made of calcium alginate are not acceptable. The swab specimen collection vials should contain one to three milliliters of viral transport medium (e.g., containing protein stabilizer antibiotics to discourage bacterial and fungal growth and buffer solution), such as M4RT or the BD Universal Viral Transport SystemExternal Web Site Policy.

All respiratory specimens should be stored at 4°C until they can be placed at -70°C. If a -70°C freezer is not available, specimens should be kept at 4°C, preferably no longer than one week. Specimens should be shipped on dry ice in appropriate packaging, labeled clearly, and provide information requested by the state public health lab.

AABB Advice to Blood Centers, Transfusion Services

The American Association of Blood Banks has issued two bulletins with recommendations for blood centers and transfusion services on the H1N1 virus. Association Bulletin #09-02 recommends that all facilities review their respective pandemic influenza plans and continue to exclude ill donors, employees, and volunteers from sites where others might be exposed to potentially transmissible infections.

Association Bulletin #09-03 gives specific recommendations on how facilities should prepare for any potential adverse impacts on the blood supply caused by the ongoing outbreak. It also offers details on how to report concerns regarding the availability of blood-related supplies and contact information for facilities interested in participating in investigations on the theoretical risk of transfusion transmission.

♦ CLIA *Advisory*

Update on Waived Tests and Billing Codes

The Centers for Medicare and Medicaid Services has added the tests cited below to the list of clinical laboratory tests approved by the Food and Drug Administration as waived under CLIA (the Clinical Laboratory Improvement Amendments). The additions include drug screening, urinalysis, chemistry, hematology and coagulaton, and microbiology tests.

Codes for these tests must be billed with the QW modifier to be recognized by local Medicare contractors as a waived test. Contractors edit laboratory claims at the CLIA certificate level, CMS noted, to ensure that Medicare and Medicaid only pay for waived tests performed in facilities that are CLIA-certified for this work.

New waived tests are approved on a flow basis and are valid as soon as they are approved. The list of CLIA waived tests and billing codes is typically updated quarterly. The latest update, implemented last month in editing claims, and the complete waived test list are presented in CMS Change Request 6370 at *www.cms.hhs.gov/transmittals*.

CPT Code	Effective Date	Description
87880QW	July 17, 2008	Henry Schein One Step+ Strep A Dipstick Test
81003QW	Oct. 17, 2008	Consult Diagnostics Urine Analyzer
82465QW (Contact your Medicare carrier for claims instructions.), 82947QW, 82950QW, 82951QW, 82952QW, 83036QW, 84478QW	Oct. 31, 2008	Wako APOLOWAKO Analyzer (Whole Blood)
83986QW	Nov. 4, 2008	Common Sense Ltd. Norma-Sense Vaginal Discharge pH Test
80101QW	Nov. 4, 2008	Mossman Associates Inc. NicCheck I Test Strips
83036QW	Nov. 13, 2008	Siemens DCA 2000 Analyzer, Siemens DCA 2000+ Analyzer
82565QW	Nov. 13, 2008	Abbott i-STAT Crea Cartridge {Whole Blood}
82947QW, 82950QW, 82951QW, 82952QW	Nov. 13, 2008	Abbott i-STAT G Cartridge {Whole Blood}
82435QW, 82947QW, 82950QW, 82951QW, 82952QW, 84132QW, 84295QW, 84520QW, 85014QW	Nov. 13, 2008	Abbott i-STAT 6+ Cartridge {Whole Blood}
82947QW, 82950QW, 82951QW, 82952QW, 84132QW, 84295QW, 85014QW	Nov. 13, 2008	Abbott i-STAT EC4+ Cartridge {Whole Blood}
84295QW, 84132QW, 85014QW	Nov. 13, 2008	Abbott i-STAT E3+ Cartridge {Whole Blood}

Medical Groups Back Universal Screening for HIV

In arguing for universal versus risk-based screening, the groups note that many patients do not know about risky behaviors or do not inform their physicians if they do engage in them. If identified late in the disease, patients will not get the maximum benefit from antiretroviral therapy.

The entire population of the United States should be routinely screened for the HIV virus so that those infected can start treatment and therapy before they become severely immunocompromised, said the American College of Physicians (ACP) and the HIV Medicine Association of the Infectious Diseases Society of America in a joint paper released last month.

The report also said Medicare and Medicaid should cover routine HIV screening for enrollees. Medicare recently announced it is considering the benefits of the testing for beneficiaries and plans to complete a national coverage analysis this year (*NIR, 09, 6/Mar 30, p. 8*). ACP released guidance earlier this year, urging doctors to begin routine HIV screening of patients at age 13, regardless of whether they engage in risky behaviors (*NIR 09, 3/Feb 9, p. 8*).

Commenting on the report, ACP president Jeffrey Harris noted that early detection not only helps individuals live to near normal life spans, but also saves money. Recent studies show that treating HIV patients before they become ill costs $13,885, while treating them after they become sick costs about $36,533.

Upcoming G-2 Events

★ Webinar ★

May 14
Negotiating Hospital-Based Contracts: What Pathologists Need to Know
2:00 – 3:30 p.m. (Eastern)

Learn new insights on reviewing and revising contracts on complex legal issues, including adequate pathologist compensation for services.

★ Conference ★

June 8-10
Laboratory Outreach 2009 Maximizing Value, Profitability, and Service
Hyatt Regency Mission Bay Spa and Marina, San Diego

For registration and program information on the above, go to www.g2reports.com

NIR Subscription Order or Renewal Form

- ❑ ***YES***, enter my one-year subscription to the *National Intelligence Report (NIR)* at the rate of $489/yr. Subscription includes the *NIR* newsletter and electronic access to the current and all back issues at *www.ioma.com/g2reports/issues/NIR*. Subscribers outside the U.S. add $100 postal.*
- ❑ AAB & NILA members qualify for special discount of 25% off — or $366.75 (Offer code NIRI1).
- ❑ I would like to save $196 with a 2-year subscription to *NIR* for $782.*
- ❑ ***YES***, I would also like to order the *Lab Industry Strategic Outlook 2009: Market Trends & Analysis* for $1,495 ($1,195 for Washington G-2 Reports subscribers). (Report #3308C).

Please Choose One:

❑ Check enclosed (payable to Washington G-2 Reports)
❑ American Express ❑ VISA ❑ MasterCard

Card # _____ Exp. Date _____
Cardholder's Signature _____
Name As Appears On Card _____
Name/Title _____
Company/Institution _____
Address _____
City _____ State _____ ZIP _____
Phone _____ Fax _____
e-mail address _____

*By purchasing an individual subscription, you expressly agree not to reproduce or redistribute our content without permission, including by making the content available to non-subscribers within your company or elsewhere.

Mail to: Washington G-2 Reports, 1 Washington Park, Suite 1300, Newark, NJ 07102-3130.
Or call 973-718-4700 and order via credit card or fax order to 973-718-0595 NIR 5/09A

 NATIONAL INTELLIGENCE REPORT (ISSN 0270-6768) is published twice monthly (except August and December, which are one-issue months) by Washington G-2 Reports, 1 Washington Park, Suite 1300, Newark, NJ 07102-3130. Telephone: (973) 718-4700. Fax: (973) 718-0595. Web site: www.g2reports.com. Order Line: (212) 629-3679.

Jim Curren, Editor; Dennis Weissman, Executive Editor; Janice Prescott, Sr. Production Editor; Perry Patterson, Vice President and Publisher; Joe Bremner, President.

Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 973-718-4700.