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Top HHS Panel Urges Fast Action On E-Lab Data Sharing

The advisory group calls for endorsed standards for vocabulary, messaging, and implementation, plus incentives to put them into use within one year.

The goal of a market-run national e-health record (EHR) system, a major priority of the Bush Administration, is to improve the quality and efficiency of healthcare by enabling clinicians to make informed decisions at the point of care. And a crucial starting point to ensure broad EHR adoption, says a key commission advising the Health & Human Services Secretary, is to ensure timely and easy access to comprehensive laboratory data.

At its May 16 meeting, the panel, known as the American Health Information Community (AHIC) and including representatives from both public and private sectors, approved a series of steps recommended by its EHR workgroup for development of standards for reporting lab test results and promotion of their use, in part by having federal programs require the standards in awards to private contractors.

The workgroup also noted that CLIA and HIPAA rules present potential barriers with regard to disclosure of lab test data, especially where state laws are more stringent. One key recommendation is to facilitate access to e-lab data by resolving variations in how "authorized persons" are defined. For more on EHRs and the sharing of lab test results, see the *Focus*, pp. 4-5.

Bill Backs Higher Molecular Diagnostic Fees

Bipartisan legislation was introduced in the House on May 11 to revamp the Medicare payment system for molecular diagnostics and other new testing technologies.

AdvaMed, the leading trade group for medical device manufacturers, strongly supports the bill, saying it is needed for widespread development and use of these technologies. The current Part B lab fee schedule is outmoded, says AdvaMed, and periodic adjustments do not take into account the added value and costs of genetic testing.

The bill—H.R. 5369, the Advanced Laboratory Diagnostics Act of 2006—would establish a demonstration project to evaluate a new Medicare payment system for molecular diagnostic tests that would "more appropriately reflect the value of these technologies to patient care management." The term "molecular diagnostic test" is defined as "a clinical diagnostic lab test performed on deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or protein that is drawn from a human being or from a disease-causing organism."

➥ *p. 2*

INSIDE *NIR*

Enactment of legislation to raise Medicare fees for molecular diagnostics and other new tests does not look likely this year, according to Capitol Hill watchers. Nonetheless, supporters say, it keeps pressure on the government to make genetic test payment a key priority for Medicare changes.

Molecular Diagnostic Fees, *from p. 1*

The legislation also would:

- ❑ Establish an appeals process to correct payment errors.
- ❑ Direct the Centers for Medicare & Medicaid Services to publish procedures and criteria for new test payment decisions via the gap-fill method. Currently under this method, the fee for a new test is set by carriers based on local pricing patterns.
- ❑ Require CMS to provide advance notice when a test is being considered for an "inherent reasonableness" adjustment. The agency has the authority to adjust Part B non-physician provider fees up or down by 15% if the fees are judged to be "grossly excessive" or "grossly deficient" (*NIR, 27, 6/Jan 9 '06, p. 4*).

H.R. 5369, co-sponsored by Republican Reps. Michael Ferguson (NJ) and Phil English (PA) and Democratic Reps. Mike Thompson (IL) and Bobby Rush (IL), has been referred to the House Energy & Commerce and Ways & Means Committees. There is no Senate counterpart bill as yet.

In praising the bill, AdvaMed president and CEO Stephen Ubl said in a statement, "This important legislation will begin to bring the 22-year-old Medicare lab payment system in line with 21st century medical science." As an example, he pointed to Medicare payment for an advanced viral load test for hepatitis C. "Payments to labs that offer the HCV test are less than the cost of performing the test," he said, "and only half the amount for performing an HIV viral load test, which requires an identical series of complex steps and resources." The HCV test measures the amount of the virus in the blood and helps the physician track the effectiveness of drugs to treat the disease.

Meantime, the HHS Secretary's Advisory Committee on Genetics, Health & Society has also come out in favor of higher Medicare fees to align genetic test prices with actual costs. In a final report to Secretary Michael Leavitt, released March 27, SACGHS urged that HHS be ready to revise fees "to reflect the true cost of a genetic test" when the current lab fee freeze ends in 2009, but for interim relief, the Secretary should direct CMS to use its "inherent reasonableness" authority to increase fees for genetic test CPT codes (*NIR, 27, 13/Apr 24 '06, p. 8*). "Patient access is threatened when genetic testing costs outstrip reimbursement rates," the panel said, citing such examples as testing for Fragile X syndrome, the most common inherited form of mental retardation, and Factor V Leiden, the most common hereditary blood coagulation disorder in the U.S.

GOP Healthcare Reforms Falter In The Senate

During a special "Health Week" held this month to highlight the GOP's legislative agenda for market-oriented healthcare reforms, the Senate Republican leadership failed to move bills to limit medical liability awards and to let small businesses form association health plans, both part of the President's strategy to lower the costs of healthcare (*NIR, 27, 13/Apr 24 '06, p. 5*).

The leadership could not muster the 60 votes needed to overcome a potential filibuster on three key bills. Some critics in the GOP said "Health Week" was a bad idea, exposing the party to charges that it could not deliver on key priorities. Still, some GOP strategists say, the effort helped sharpen the party's position ahead of the November elections. Democrats joined ranks to squelch the bills and chided GOP leaders for not letting them bring up their own priorities, including extending

the May 15 deadline to enroll in the Medicare drug benefit and providing support for stem cell research.

Small Business Association Plans

S. 1955, sponsored by Sen. Mike Enzi (WY), chair of the Health, Education, Labor & Pensions Committee, was stalled by a vote of 55-43 on May 11. Enzi said his bill would make health insurance more affordable to small businesses by letting them leverage their group purchasing power to get competitive coverage bids. Insurers choosing to bid would have to offer a plan with benefits similar to a plan offered in one of the five most heavily populated states—California, Texas, Illinois, Florida, and New York.

The defeats in the Senate pretty much nix the prospects for passage this year of medical liability limits and small business association health plans, analysts say, given the bitter partisan divide in Congress and the short legislative time left before the November elections.

There is agreement that small companies employ a disproportionately large number of the uninsured, and that by forming purchasing pools they could save on healthcare coverage costs and afford to offer it to their workers. But Enzi's bill ran into strong opposition because it would allow small business groups to buy coverage across state lines and get around state-required consumer safeguards, such as mandated benefits and curbs on premium hikes. Some cancer screenings could be threatened, AARP warned, while the American Diabetes Association warned of higher premiums for those with diabetes and other chronic diseases. Enzi argued, to no avail, that his bill would produce savings by lowering administrative costs, not by stripping benefits.

Medical Liability Limits

On May 8, two Senate bills that would have imposed limits on jury awards for non-economic (pain and suffering) damages in medical malpractice cases also fell short of the 60-vote supermajority:

- S. 22, a revised bill sponsored by Sen. John Ensign (R-NV), would have capped non-economic damages at $250,000 in most cases, with an upper limit of $750,000 for cases involving multiple medical facilities. Lawsuits would have to be filed within three years of the alleged injury. The final vote was 48-42.
- S. 23, sponsored by Sen. Rick Santorum (R-PA), would have capped non-economic damages at similar levels in lawsuits filed against obstetricians-gynecologists. The final vote was 49-44.

In both bills, punitive damages would be allowed only in malpractice suits in which the defendants acted "with malicious intent to injure the claimant" or "deliberately failed to avoid unnecessary injury."

Limits on medical liability awards, long a GOP priority, have passed the House several times (the last time was in July 2005), but similar legislation has faltered in the Senate over the past two years. Supporters say a flood of "frivolous" lawsuits is forcing some physicians out of practice, in particular ob-gyns, and driving up premiums for others. Supporters also contend that such lawsuits drive up costs by forcing doctors to practice "defensive" medicine, including ordering extra laboratory, pathology, and other services.

Opponents dispute the notion that out-of-control jury awards contribute to rising malpractice insurance costs. Some argue there is no premium crisis. A study in the journal *Health Affairs* (April 9) concluded that premium costs have declined in inflation-adjusted dollars to an average $18,400 in 2000 from an average $20,106 in 1986. The researchers did note a premium rise between 1996 and 2000, but said it had little impact on practice expenses or net practice income nationally, within regions, or within practice specialties.

focus on: Health Information Technology

Accelerating The Drive For EHR Lab Data Exchange

Nearly every healthcare entity developing an e-health infrastructure is "looking to laboratories first … Labs and the medical information they provide are the heart of the medical record"—ACLA president Alan Mertz in testimony before the House Energy & Commerce health subcommittee.

The special commission advising Health & Human Services Secretary Michael Leavitt on development of a national electronic health record (EHR) system has endorsed a series of recommendations to deploy, within a year, standardized and secure solutions for electronic sharing of lab test results and interpretations by authorized parties for clinical care purposes.

At its May 16 meeting in Washington, DC, the 17-member panel—chaired by Leavitt and known as the American Health Information Community (AHIC)—acted on proposals from its EHR workgroup and three others (chronic care, consumer empowerment, and biosurveillance). The workgroups were charged with devising "breakthrough" applications of health information technology that could be fielded quickly to benefit healthcare providers, payers, and patients.

AHIC is a major component of the effort by HHS and its Office of the National Coordinator for Health Information Technology (ONCHIT) to spur public and private collaboration toward the President's goal of having an EHR for most Americans within 10 years. The anticipated benefits of switching from the current largely paper-based system to a "cradle to grave" EHR system include better quality of care, reduced medical errors, less duplication of diagnostic testing and other medical services, administrative cost savings, and better tracking of disease outbreaks and other public health threats.

EHR Recommendations

In presenting its recommendations, the EHR workgroup said the ultimate goal is to make laboratory data available in a patient-centric model, "where a patient's lab test results are available to all authorized providers of care, regardless of where or when the information was generated." The target date: March 31, 2007.

To get to this point from the current provider-centric model, "where only the lab data ordered by a specific provider for a specific patient are available for review," recognized standards are required to promote interoperability and reduce the need for costly customized interfaces.

"A big part of AHIC's drive is to get uniform standards to help take the guess-work out of adoption for providers," Jason DuBois told *NIR*. DuBois is vice president for government relations at the American Clinical Laboratory Association. ACLA is represented on the EHR workgroup by its president and CEO Alan Mertz. The association also serves on the biosurveillance workgroup on an ad hoc basis.

"Many providers worry, among other things, whether the hardware or software they adopt today will be a 'dinosaur' tomorrow," DuBois said. "With standards in place, physician adoption will increase significantly from the relatively slow rate of adoption today, now in the neighborhood of 15% to 17%." In its letter to Leavitt, the

"Lab test results have the unique feature of currently existing in electronic format, though they are generally sent to physician offices by fax. Since these results are a component of 70% of clinical decisions, timely and easy access to comprehensive lab data is of high value to clinicians"—EHR workgroup letter to HHS Secretary Leavitt.

EHR workgroup said that lab-to-practice connectivity has been elusive in the small practice setting. "Much has been blamed on the high cost of custom interfaces estimated at $30,000 to $50,000 per lab and $20,000 per interface in a group practice."

AHIC accepted the workgroup's recommendation that the HIT Standards Panel (HITSP) should identify and endorse vocabulary, messaging, and implementation standards for reporting the most commonly used lab test results by September 2006, so they can be included in the CCHIT interoperability criteria for March 2007 certification.

HITSP is under contract with HHS to harmonize standards to support interoperability among healthcare software applications. CCHIT is a certification body, also under contract with HHS, to objectively evaluate EHR product capabilities, including the infrastructure and network components through which they interoperate—currently, more than 200 of these products are marketed by different vendors. CCHIT is expected to release results of its first certification testing in July.

AHIC called on federal healthcare delivery systems that provide direct patient care to develop a plan to adopt HITSP-endorsed standards for lab data interoperability by December 31, 2006. Also, federal agencies with health lines of business should include incentives for use of these standards in their contracts with vendors, where applicable.

One major issue requiring further work, AHIC said, is how to remove barriers that HIPAA and CLIA rules pose to the sharing of lab test results. HIPAA privacy rules generally let health plans, providers, and health clearinghouses disclose protected health information to treat and manage disease. But the rules do not preempt stricter federal or state disclosure laws.

Under CLIA, labs may disclose test results only to individuals authorized under state law to order tests or receive results, or both, and if applicable, the individual responsible for using the results and the lab that initially requested the test (for example, reference labs). Many states limit a lab's disclosure of test results only to the ordering physician, but are silent on disclosure to others caring for the patient.

AHIC agreed to work further with ONCHIT staff to resolve these issues, which involve both statutory and regulatory changes. The EHR workgroup noted that for electronic historical lab results to be available in a patient-centric model, "various architectural models (such as Web portals and regional health information exchanges) must be evaluated in the light of CLIA and HIPAA."

Further work is also needed, AHIC said, on issues impacting the confidentiality and security of EHRs. These include technical considerations such as patient and provider authorization and authentication (including accurate patient identification and linkage to patient-specific information), as well as policies governing privacy and security breaches.

AHIC tabled for now the EHR workgroup's proposals for developing a business case for lab data sharing and for joint monitoring of the initial rollout of HITSP standards and research into best practices by HHS's Agency for Healthcare Research & Quality, the Centers for Disease Control & Prevention, and the Centers for Medicare & Medicaid Services.

President Enlists Medicare In Price Transparency Push

"We're also asking doctors, hospitals, and other providers to post their walk-in prices to all patients," Bush said.

President George W. Bush has announced that beginning June 1, Medicare provider pricing and quality information will be available on the Web, as part of his Administration's initiative to help curb rising healthcare costs by empowering consumers as "smart shoppers."

In announcing the Web posting at the annual meeting of the American Hospital Association earlier this month, the President urged hospital executives to also make more information on price and quality available to patients.

"We're also asking insurance companies to increase transparency by providing their negotiating prices and quality information to their enrollees," Bush said, adding that the Federal Government will "require transparency from insurance plans participating in federal programs. Beginning this year, the Federal Employees Health Benefits Program and the military's Tricare system are asking contractors to begin providing price and quality information."

Price transparency is especially crucial for individuals who invest in health savings accounts (HSAs) to pay for their own care, he noted. "To be smart consumers and … spend their HSA dollars wisely, [they] need to know in advance what their medical options are, the quality and expertise of the doctors and hospitals where they live, and what their medical procedures will cost."

The AHA, which represents 4,800 hospitals, said its policy on transparency is to present price and quality information that is easy for consumers to understand and use. That means common terms, definitions, and explanations about how and why the price of care can vary. But price is just one factor that individuals consider when making healthcare decisions, the AHA cautioned.

The Association said it supports federal requirements to expand on current state and private efforts to publish hospital charges and patients' out-of-pocket costs under insurance plans. Some 32 states already require hospitals to publicly report pricing information, the AHA noted. Separately, the for-profit HCA hospital chain and the Federation of American Hospitals, which represents for-profit hospitals, pledged to work with the Administration to expand price and quality transparency.

The type of health insurance that consumers have will also impact their desire for pricing information in advance of receiving care, such as how much they will have to pay out-of-pocket. Currently, private plans typically show the provider's charge, the negotiated payment rate, and any applicable co-insurance after the service is performed. In states where consumers may order certain lab tests and get the results, facilities offering direct access testing usually operate on a private-pay basis, with test menu prices furnished in advance.

Massachusetts Restores Employer Assessment

Now that the Democrat-controlled Senate in Massachusetts on May 4 voted, 31-9, to override GOP Gov. Mitt Romney's line-item veto, the employer assessment has been restored to the state's legislation to expand healthcare coverage to the uninsured. The Democrat-run House overrode the veto on April 25 (*NIR, 27, 14/May 8 '06, p. 7*).

The employer assessment, together with the requirement that individuals purchase healthcare coverage, are the key components of the Massachusetts plan to reach virtually all uninsured residents within three years.

The legislation combines an individual mandate with an employer mandate (*NIR, 27, 13/Apr 24 '06, Focus, pp. 4-5*). As of July 1, 2007, all state residents will be required to purchase healthcare coverage or forfeit certain state income tax advantages. All employers that have 11 or more workers and do not provide health insurance to them will be required to pay an annual assessment of up to $295 per employee.

Meanwhile, to secure $385 million in Medicaid reimbursement that is a key portion of the funding estimated to support expanded healthcare coverage, the state has submitted its reform plan to the Centers for Medicare & Medicaid Services and has asked CMS to expedite review and approval by July 1, the target date for securing the money.

Under the timeline in the state plan, an agency to coordinate provision of health insurance coverage for individual residents will be up and running between May and October and will begin offering products by January. Open enrollment will start next March.

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New CLIA-Waived Tests

In the latest update of the list of clinical laboratory tests that the Food & Drug Administration has approved as waived under CLIA, local Medicare contractors have been notified by the Centers for Medicare & Medicaid Services to recognize the following waived test CPT billing codes, effective June 12, 2006:

• Drug Testing

80101QW First Check Diagnostics First Check 12 Drug Test
80101QW Biotechnostix Rapid Response MultiDrug, Multi-Line Screen Test Card with Integrated Cup
80101QW First Check Diagnostics First Check Multi-Drug Cup
80101QW Biotechnostix Rapid Response One Step Multi-Drug, Multi-Line Screen Test Device

• Urine Screening/Diabetes, Kidney Disease, Urinary Tract Infection

81003QW, 82570QW Bayer Clinitek Status Urine Chemistry Analyzer

• Follicle Stimulating Hormone

83001QW Biotechnostix, Inc. Rapid Response FSH One Step Menopause Test Device

• Diabetes Monitoring

83036QW Axis-Shield Afinion AS100 Analyzer

• Infectious Mononucleosis

86308QW RAC Medical Clarity MONO Mononucleosis Rapid Test Device {Whole Blood}
86308QW Icon Mono

Source: CMS Change Request 5083, May 12, 2006

Hold On Medicare Payments

As we previously reported, Medicare is taking a holiday from paying its bills for nine days at the end of September (*NIR, 27, 10/Mar 13 '06, p. 7*). But if you want the official word on how this will affect your accounts receivable, you need to access CMS Change Request 5047, dated May 10, 2006, which rescinds previous instructions to local contractors (CR 4349, February 10, 2006). CR 5047 corrects a business requirement and restates the "payment hold" policy. As required by the Deficit Reduction Act of 2005, payment on Medicare claims must be held from September 22 through September 30, 2006, and will be paid on October 2. No interest or late penalty will be paid to an entity or individual for any delay in a payment caused by the one-time hold.

Medicare's 45% Trigger: A New Potential Threat To Lab Fees

According to the Medicare Trustees latest annual report, the funding for Part A hospital care is expected to be exhausted in 2018, two years earlier than the trustees estimated last year. Rising healthcare costs, the growing elderly population, and the new Part D drug benefit are chief causes. News that Medicare is veering toward bankruptcy sooner rather than later has become a familiar refrain.

But what's significant for laboratories, pathologists, and other providers in this year's dire forecast is in the fine print. The report for 2006 presents the first warning of impending Medicare cuts under a 45% trigger approved in the Medicare reform law of 2003. If next year's report sounds a second warning, then the President would be required to propose legislation in early 2008 to reduce spending, and Congress would have to consider the bill on a fast track.

Medicare is financed by payroll taxes, beneficiary premiums, special state payments to Part D, and general revenues. When general revenues exceed 45% of program outlays, spending cutbacks must be considered to bring the general revenue share below that threshold. This opens the door to proposed cuts across the board or in selected sectors, and Part B lab spending traditionally has been a tempting target, industry sources warn. The 45% limit will initially be breached in fiscal 2012, the trustees warn.

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The cost of blood and blood products has doubled since 2001, largely due to improved technologies and blood safety efforts. Yet too often, federal and private reimbursement has failed to fully cover these increased expenses. To help control costs, some hospitals have developed effective utilization strategies to reduce waste and managed use of blood and blood products through evidence-based practice guidelines.

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