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Certain Hospital-Based Physicians Eligible for HIT Bonuses

A new law opens the door for those in outpatient settings to qualify for health information technology bonuses that are set by law to begin next year.

Congress has clarified that hospital-based pathologists and other physicians who practice primarily in outpatient settings are eligible for Medicare or Medicaid financial incentives to adopt and make "meaningful use" of certified electronic health record technology, starting in 2011.

The financial incentives were approved as part of the economic stimulus package, the American Recovery and Reinvestment Act of 2009 (Public Law 111-5). It provided bonus payments for hospitals and physicians to embrace health information technology (HIT), with early adopters reaping the most.

But certain provisions were subsequently construed to exclude HIT bonuses to all hospital-based physicians, including pathologists, but allow pathologists in independent practice to qualify.

In the Health Care and Education Reconciliation Act (Public Law 111-157), lawmakers redefined "hospital-based eligible professional" to stipulate that only hospital-based physicians who provide services in a hospital inpatient or emergency room setting are excluded from receiving direct HIT payments. *Continued on p. 2*

NIH to Establish a Genetic Testing Registry

The National Institutes of Health (NIH) is creating a public database that researchers, consumers, health care providers, and others can search for information submitted voluntarily by genetic test providers, including clinical laboratories, test manufacturers, and entities that report and interpret tests performed elsewhere.

The Genetic Testing Registry (GTR) is to be developed with stakeholder input this year and is expected to be available in 2011.

Currently, more than 1,600 genetic tests are available to patients and consumers, but there is no single public resource that provides detailed information about them, NIH said. The new registry is intended to fill that gap.

Key Operational Facts

- **Working definition:** A genetic test is defined as "a test that involves an analysis of human chromosomes, deoxyribonucleic acid, ribonucleic acid, genes and/or gene products (e.g., enzymes and other types of proteins), which is predominantly used to detect heritable or somatic mutations, genotypes, or phenotypes

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Certain Hospital-Based Physicians, *from p. 1*
They are considered to be covered under the HIT payment to the hospital and must negotiate their share with the hospital.

Medicare-participating pathologists and other eligible professionals are entitled to direct HIT incentive payments of up to $44,000 over five years, starting in 2011. Those who sign on early gain the most. If the first payment year is 2011 or 2012, the bonus is $18,000. Otherwise, it is $15,000 for the first payment year.

Meantime, the American Society for Clinical Pathology (ASCP) has urged the Centers for Medicare and Medicaid Services (CMS) to make major changes to proposed rules on "meaningful use" of certified electronic health records.

Requiring all participating physicians to report data on 25 health information technology functionality measures and two separate clinical quality requirements would likely prevent pathologists from participating in the program, ASCP said.

Pathologists might only be able to report data on a few of the 25 HIT measures. These focus on primary care and require reporting patient information that the pathologist or laboratory would not likely possess, such as patient demographics and vital signs.

Further, the clinical quality measures require data on a predefined set of core measures that would be difficult for pathologists to satisfy, ASCP continued. These measures are preventive care and screening for tobacco use, blood pressure measurement, and drugs to be avoided in the elderly.

ASCP also expressed concern that the excessive cost of setting up operational interfaces ($5,000 to $15,000) between each ordering provider and a lab "could force small- and medium-sized labs from the market."

For example, CMS proposed requiring that "at least 50 percent of all clinical lab test results ordered by the [eligible professional] . . . are incorporated in certified EHR technology as structured data." This should be phased in over the three regulatory stages of the program.

These twin reporting problems also present a downstream issue, the society warned. Failure to participate in the program could cut pathology reimbursement by 3 percent, beginning in 2015.

ASCP urged that pathologists be exempted from the HIT functionality measures and the clinical care measures. Given the reliance of other physicians on pathology and laboratory information, pathologists and labs providing information electronically to their clients should be deemed as meeting reporting requirements.

ASCP also stated that if CMS plans to cut reimbursement for nonparticipation, it has an obligation to craft an incentive program in which all physicians can participate.

Lastly, ASCP argued that hospital-based physicians who have to pay the costs for their own electronic health record (EHR) technology or for interfacing their laboratory information systems with other EHRs should be eligible for incentive payments.

focus on: Health Care Reform

Accelerating the Shift to Prevention and Wellness

Medicare's Preventive Services Benefit

New in 2011

- ❑ Annual wellness visit with personalized prevention plan services

Currently Covered

- ❑ "Welcome to Medicare" initial preventive physical exam
- ❑ Screening tests for:
  - – Abdominal aortic aneurysm
  - – Breast cancer: mammograms, Pap smears
  - – Cervical or vaginal cancer: pelvic exam, plus clinical breast exam
  - – Cardiovascular disease (lipids)
  - – Colorectal cancer, including fecal occult blood test
  - – Diabetes and diabetes self-management training
  - – HIV infection
  - – Prostate cancer: prostate-specific antigen test, digital rectal exam
  - – Glaucoma
  - – Osteoporosis: bone mass measurements
- ❑ Medical nutrition therapy
- ❑ Smoking and tobacco-use cessation counseling
- ❑ Vaccinations: influenza, pneumococcal, hepatitis B

New policy initiatives in the health care reform law that emphasize primary care and prevention aim to tilt incentives in the nation's health care system toward improving the quality of life for patients and achieving service delivery efficiencies.

The goal of numerous provisions in the law—the Patient Protection and Affordable Care Act (PPACA, Public Law No. 111-148)—is to reduce and manage disease complications and avoid costly hospitalizations while rewarding quality and cost-saving outcomes.

For clinical laboratories and pathologists, these initiatives pose both immediate and long-term challenges. The testing market will grow now and in the future as health care coverage expands to an estimated 94 percent of Americans. The coverage will be required to include a range of preventive services mandated for Medicare and qualified private health plans, including laboratory testing and other screening procedures.

The law also gives new prominence to the role of the U.S. Preventive Services Task Force (USPSTF) and its rating of preventive services as A (strongly recommended) or B (recommended).

Medicare may add these services to its preventive services benefit. Qualified health plans that participate in new health exchange networks to be established will be required to offer these services, as well as other recommended screenings and immunizations.

On the immediate horizon, Medicare is authorized to add an annual wellness visit, with health risk assessment, in 2011, and to waive most beneficiary cost sharing, as of Jan. 1, 2011.

Further, over years 2011 through 2013, Medicare is to start a series of new demonstration projects that test new models for delivering and paying for primary care and prevention services, including the medical home model, bundled payment for services per episode of care, and the accountable care organization model that allows providers to share in the savings to Medicare through improved patient outcomes and program efficiencies (*NIR 10, 8/April 23, pp. 3-6*).

Boost for Preventive Services Task Force

The health care reform law puts a premium on services recommended by the U.S. Preventive Services Task Force (USPSTF). Medicare may decide to cover additional screening tests with an A or B rating, while group and individual health plans will be required to cover services rated A or B, along with other recommended preventive services and immunizations.

The task force is an independent panel of private-sector experts charged with assessing the scientific evidence for the effectiveness of a broad range of clinical preventive services, including screening, counseling, immunizations, and medications, which may vary by age, gender, and risk factors for disease.

The task force grades the strength of the evidence as A (strongly recommends), B (recommends), C (no recommendation for or against), D (recommends against), or I (insufficient evidence to recommend for or against).

The current panel has 12 members drawn from primary care and prevention fields and has numerous partners in medical specialty organizations and federal agencies.

The reform law requires broader representation of clinical specialties on the task force. It also requires the panel to update previous recommendations by considering best practices from government agencies, professional medical societies, patient groups, and scientific societies. The Clinical Laboratory Coalition was among those that lobbied for this wider input in the USPSTF decisionmaking process (*NIR 09, 11/June 8, p. 5*).

The USPSTF is administered by the Agency for Healthcare Research and Quality (AHRQ) within the Department of Health and Human Services. It is supported by an Evidence-based Practice Center, which, under contract to AHRQ, conducts systematic reviews of the scientific evidence for the task force recommendations.

Medicare Authorized to Cover Annual Wellness Visit

Currently, Medicare covers a one-time "Welcome to Medicare" baseline physical exam for beneficiaries within 12 months of their Part B enrollment. This initial preventive physical exam (IPPE) includes education, counseling, and referrals for clinical lab and physician services included in the Part B preventive services benefit.

But as of Jan. 1, 2011, Medicare is authorized to cover subsequent routine checkups payable under the Part B physician fee schedule with no cost sharing by beneficiaries when provided in outpatient settings. This annual wellness visit is to provide the beneficiary with personalized prevention plan services, including a comprehensive health risk assessment.

The plan can include several elements: medical and family history, identification of health risk factors, and a screening schedule for the next five to 10 years, as appropriate, based on recommendations of the USPSTF and the Advisory Committee on Immunization Practices and the individual's health status, screening history, and age-appropriate preventive services covered by Medicare.

The Health and Human Services (HHS) secretary is required to publish guidelines for the health risk assessment by no later than March 23, 2011, and a health risk assessment model by no later than Sept. 29.

The cost of adding the annual wellness visit is an estimated $1.4 billion over five years and $3.6 billion over 10 years, according to the Congressional Budget Office scoring of this provision.

Medicare to Drop Most Beneficiary Cost Sharing

Starting next year, the annual deductible and copayment for many, but not all, Medicare-covered preventive services are waived, with Medicare picking up 100 percent of the tab and relieving providers of having to bill the beneficiary for 20 percent of the services payable under the physician fee schedule. Providers who bill for covered services payable under lab fee schedule are not affected. These services already are not subject to an annual deductible or a 20 percent copay.

The law defines Medicare-covered preventive services to mean a specified list of currently covered services, including colorectal cancer screening even if diagnostic or treatment services were furnished in connection with the screening, as well as the new annual wellness visit, with personalized prevention plan services.

U.S. Preventive Services Task Force
Services Rated A (Strongly Recommended) or B (Recommended)

	Adults		Special Populations	
Recommendations	**Men**	**Women**	**Pregnant Women**	**Children**
Abdominal aortic aneurysm, screening	✔	-	-	-
Alcohol misuse screening, behavioral counseling interventions	✔	✔	✔	-
Aspirin to prevent cardiovascular disease	✔	✔	-	-
Asymptomatic bacteriuria in adults, screening	-	-	✔	-
Breast cancer screening	-	✔	-	-
Breast, ovarian cancer susceptibility, genetic risk assessment, and BRCA mutation testing	-	✔	-	-
Breastfeeding, primary care interventions to promote	-	✔	X	-
Cervical cancer screening	-	✔	-	-
Chlamydial infection, screening	-	✔	✔	-
Colorectal cancer screening	✔	✔	-	-
Congenital hypothyroidism, screening	-	-	-	✔
Dental caries in preschool children, prevention	-	-	-	✔
Depression (adults), screening	✔	✔	-	-
Diet, behavioral counseling in primary care to promote healthy lifestyle	✔	✔	-	-
Gonorrhea, screening	-	✔	✔	-
Gonorrhea, prophylactic medication	-	-	-	✔
Hearing loss in newborns, screening	-	-	-	✔
Hepatitis B virus infection, screening	-	-	✔	-
High blood pressure, screening	✔	✔	-	-
HIV screening	✔	✔	✔	✔
Iron deficiency anemia, prevention	-	-	-	✔
Iron deficiency anemia, screening	-	-	✔	-
Lipid disorders in adults, screening	✔	✔	-	-
Major depression disorder in children and adolescents, screening	-	-	-	✔
Obesity in adults, screening	✔	✔	-	-
Osteoporosis in postmenopausal women, screening	-	✔	-	-
Phenylketonuria, screening	-	-	-	✔
Rh(D) incompatibility, screening	-	-	✔	-
Sexually transmitted infections, counseling	✔	✔	-	✔
Sickle cell disease, screening	-	-	-	✔
Syphilis infection, screening	✔	✔	✔	-
Tobacco use and tobacco-caused disease, counseling	✔	✔	✔	-
Type 2 diabetes in adults, screening	✔	✔	-	-

Source: *Guide to Clinical Preventive Services, 2009*, U.S. Preventive Services Task Force. Services subject to certain age, gender, and risk factor requirements as well as frequency limits.

The copayment is waived for these defined services, any additional preventive service covered under the administrative authority of the HHS secretary, and any currently covered preventive service (including medical nutrition therapy but excluding electrocardiograms) if recommended with a grade of A or B by the USPSTF.

The law makes one change regarding USPSTF recommendations for breast cancer screening, mammography, and prevention. It rejects the November 2009 recommendation that routine screening for women begin at age 50 and retains the panel's previous recommendation to begin routine screening at age 40.

The deductible is waived for the preventive services noted above for which the copayment is waived. However, the deductible is not waived for any additional preventive service covered under the secretary's administrative authority.

The beneficiary cost sharing changes will cost $0.3 billion over five years and $0.8 billion over 10 years, the Congressional Budget Office estimates.

CMS May Modify Preventive Services Benefit

Since Jan. 1, 2009, the Centers for Medicare and Medicaid Services (CMS) has had the authority to add services to the Part B preventive care benefit without congressional approval as long as certain requirements were met, including having a service rating of A or B by the USPSTF.

To date, CMS has used this power once, adding HIV screening of individuals at high risk of infection and all pregnant beneficiaries, effective Dec. 8, 2009.

Now, CMS is given new authority to modify evidence-based coverage of the Part B preventive services benefit (excluding the baseline physical exam) to be consistent with the USPSTF recommendations. CMS also may withhold payment for covered services rated D (not recommended).

National Promotion of Prevention and Wellness

Pathology and clinical lab advocacy groups will be closely watching how HHS implements the reform law's call for a national public-private partnership to conduct an outreach and education campaign to raise public awareness of health improvement across the life span.

In 2011, CMS is to establish a National Prevention, Health Promotion, and Public Health Council to develop a national strategy for this purpose. The effort will be supported by a Prevention and Public Health Fund for which $7 billion is approved for fiscal years 2010 through 2015 and $2 billion for each fiscal year thereafter.

Employer Incentives

The reform law offers incentives to employers to support wellness programs for their employees. In 2011, it provides grants for up to five years to small employers that establish such programs.

In 2013, employers may offer employees rewards of up to 30 percent, increasing to 50 percent if appropriate, of the cost of coverage for participating in a wellness program and meeting certain health-related standards. Also, 10 pilot programs are authorized to allow participating states to apply similar rewards for participating in wellness programs in the individual market.

Currently, more than 1,600 genetic tests are available to patients and consumers, but there is no single public resource that provides detailed information about them, NIH said. The new registry is intended to fill that gap.

NIR to Establish, *from p. 1*

related to disease and health."

- **Voluntary participation:** Submissions will be voluntary. Those submitting will be solely responsible for the content and quality of the data they provide. The registry will incorporate quality assurance safeguards and checks against inadvertent submitter error, but NIH will conduct no further review. Test providers will be encouraged to provide explicit molecular information about the test they perform and to cite published support for their assertions to help the public evaluate the data.
- **Types of information sought:** A wide variety of information can be submitted regarding the breadth of available genetic tests—including what tests are available, indications for testing, and who offers the tests—and quality measures such as analytical validity, clinical validity, and clinical utility. GTR data will be integrated with other related NIH databases to facilitate research.
- **How to reference tests:** Each test in the registry will be assigned a unique accession number, allowing for uniform reference to tests across various entities, including scientific publications and electronic health records.
- **Data collection:** Testing information will be gathered and managed using an online submission system. Alternatives will be made available to those providers who are not able to access online systems.
- **No cost or charge:** Testing providers can submit information regarding a single test or multiple tests at no charge. Nor will there be a charge to access information contained in the registry.
- **Ordering a test:** The GTR will help health care providers and consumers determine what tests are available and provide contact information for test providers. The registry will also help identify health care professionals who can assist with the testing process and other resources such as referral information for community support groups and disease information.
- **Project oversight:** The NIH director's office will oversee the GTR project, which is to be developed by the National Center for Biotechnology Information (NCBI), part of the National Library of Medicine at NIH. Updates on the Genetic Testing Registry are available at: *http://www.ncbi.nlm.nih.gov/gtr/*.

Reform Law Imposes New Excise Tax on Medical Devices

During the debate over health care reform, clinical laboratories escaped a proposed 20 percent copay for Medicare-covered services and a proposed $750 million annual levy on their services, starting in 2010.

But they will be hit with a new 2.3 percent excise tax that the final health care reform legislation imposes on the sale of medical devices approved by the Food and Drug Administration. The tax will apply to reagents, kits, and equipment that labs purchase after Dec. 31, 2010, and will be collected at the point of sale. Exempt from the tax are eyeglasses, contacts, hearing aids, and other devices purchased by the general public at retail.

The tax is levied on medical devices as defined by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act and regulated by the FDA Center for Devices and Radiologic Health.

New Tax Credits, Grants for Research by Life Science Companies

The Treasury is to announce guidance on the application process and selection criteria by May 21, 2010. Once the program is in place, the Treasury must approve or deny applications within 30 days of submission.

Tucked into the comprehensive health care reform law is a provision that appropriates up to $1 billion in tax credits and grants to reduce the costs of therapeutic research by small and midsized life science companies, defined as having 250 or fewer employees at the time the application is submitted.

Those who apply have a choice of an income tax credit or a cash grant of up to 50 percent of a company's costs in 2009 and 2010 that are directly related to a "qualifying therapeutic discovery project," according to an analysis by tax attorney Travis T. Blais with Mintz Levin. The project is to be designed to:

- ❑ Treat or prevent diseases or chronic conditions by conducting preclinical activities and clinical trials to obtain approval by the Food and Drug Administration and the Public Health Service.
- ❑ Develop molecular diagnostics to guide therapeutic decisions.
- ❑ Develop a product, process, or technology to further the delivery or administration of therapeutics.

Goverment agencies and certain tax-exempt entities are not qualified.

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