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HIT Payment Incentives Included in Economic Recovery Act

The act also protects the health care coverage of millions of Americans through additional federal Medicaid spending and new subsidies to help workers who have lost their jobs keep their health insurance.

Clinical laboratories and certain pathologists are among those eligible for new incentive payments to adopt health information technology (HIT) that were approved in the $787 billion economic stimulus bill signed into law by President Obama on Feb. 17.

The American Recovery and Reinvestment Act provides some $20 billion in Medicare and Medicaid funding to help hospitals, physicians, and other health care providers adopt HIT, which Obama hailed as a vital investment in modernizing the health care infrastructure and improving the quality of care.

"Computerizing America's medical records is a long overdue step to reduce the duplication and waste that costs billions of health care dollars and the medical errors that every year cost thousands of lives," the president said. The HIT provisions are estimated to save $12 billion over 10 years, according to a White House statement. *Cont., p. 2*

INSIDE *NIR*

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CMS Issues Instructions on Applying Anti-Markup Rules to Diagnostic Test Claims

If you are billing Medicare for certain diagnostic tests payable under the physician fee schedule, you will see changes in how your claims for these services are processed by your local contractors, in accord with anti-markup rules recently finalized by the Centers for Medicare and Medicaid Services.

New instructions went out this month from CMS to contractors, explaining the policy on determining when and how the anti-markup pricing limits apply to the technical component (TC) and the professional component (PC) of diagnostic testing payable under Part B.

The limits apply when the diagnostic service is performed by one physician or supplier and billed by another physician or supplier in cases where a physician does not share a practice with the billing physician or other supplier.

When the limits apply, Medicare payment will be the lowest of the following (less any applicable deductible or coinsurance):

- ❑ The performing supplier's net charge to the billing physician or other supplier (excluding any charge related to the cost of space or equipment leased from or through such physician or other supplier); *Cont., p. 6*

Economic Recovery Act, *from p. 1*

The pot of money for HIT adoption includes portions exclusive to physicians, hospitals, and "other health care providers." Physicians, for example, can receive $40,000 to $65,000 to help cover costs associated with adopting HIT, noted the College of American Pathologists. Physicians will demonstrate that they are "meaningfully" using HIT, including electronic medical records, through the reporting of quality measures.

For pathologists, the site of service will make a difference in qualifying for the incentive payments, without regard to any employment or billing arrangements, noted Justin Herman, who heads communications advocacy for CAP.

While independent pathologists are eligible, hospital-based pathologists are specifically excluded from directly receiving Medicare HIT incentives out of concerns over duplicate payments, he said.

While clinical laboratories are included in the law's definition of "other health care provider," they may not be big users of the incentive payments, Jason DuBois, vice president of government relations at the American Clinical Laboratory Association, told *NIR*.

Many labs already have established extensive HIT links, he noted. The national lab companies, Quest Diagnostics and LabCorp, have long had their own systems to do business electronically with customers, while smaller labs find it easier to contract the HIT work out.

HIT incentive payments will be phased out over time, and Medicare payments will be reduced for those who do not use certified electronic health records that allow them to electronically communicate with others.

Also on the HIT front, the law requires the government to develop standards to allow for the nationwide electronic exchange and use of health information.

Other Health Care Provisions in the Economic Stimulus Package

- ❑ Provides $87 billion in additional Medicaid funding for states, which will keep an estimated 20 million individuals from losing coverage.
- ❑ Provides $24.7 billion to help an estimated 7 million individuals who lose their jobs keep their health insurance under COBRA. The government will provide a 65 percent subsidy of the premium for nine months; however, this applies only to workers who have lost their jobs since Sept. 1, 2008.
- ❑ Provides $500 million for nursing and health professions training. This includes $300 million for the National Health Service Corps, which provides scholarships and education loans for nurse practitioners, certified nurse-midwives, primary care physicians, and other health professionals. The remaining $200 million will be divided between HRSA Nursing Workforce Development programs—such as the Scholarships for Disadvantaged Students program and the Faculty Loan Repayment Program/Minority Faculty Fellowship program—and health professions training programs.
- ❑ Provides $1.1 billion for comparative effectiveness research to determine which treatments, therapies, and other clinical interventions work best for individuals and specific patient populations.

ACLA Urges the FDA to Deny Genentech's LDT Petition

Though the petition calls for FDA oversight of only lab-developed tests intended for use in drug or biologic therapeutic decisionmaking, it encompasses the great majority of LDTs, totaling thousands of tests, ACLA noted. The FDA currently regulates analyte-specific reagents used in LDTs and a category of LDTs known as IVDMIAs (in vitro diagnostic multivariate index assays) that use a proprietary algorithm to produce a patient-specific result.

The American Clinical Laboratory Association is urging the Food and Drug Administration to deny a citizen petition filed by Genentech to require that certain lab-developed tests (LDTs) be regulated by the agency.

In a 24-page response to the FDA on Feb. 19, ACLA said Genentech's petition, if accepted, would impose a "new, unnecessary regulatory framework on all LDTs," hindering the ability of clinical labs "to incorporate medical innovations quickly and effectively into patient care, provide rapid response to disease outbreaks, and provide treatment guidance for patients with rare diseases or in other situations where no FDA-cleared test exists."

Genentech, a developer of cancer drugs based in South San Francisco, Calif., wants the FDA to subject LDTs, developed by labs for in-house testing, to the same scientific and regulatory standards, including premarket review and post-market surveillance, that the agency applies to in vitro diagnostic tests developed and sold by device makers as test kits. Further, Genentech wants the FDA to simultaneously initiate enforcement action against "any clinical lab or other company that is selling an LDT or making claims about its potential indication for use, effectiveness, or value … without sufficient analytical and clinical evidence to support such claims" (*NIR, Vol. 09, Iss. 1, Jan. 12 '09, p. 1*).

ACLA challenged assertions by Genentech that LDTs pose the risk of harm to patients, noting that this is not evidenced in medical or litigation records. Rather, LDTs have a well-documented history of enhancing the quality of care and improving outcomes for patients, ACLA said, citing as examples DNA sequencing assays, karotype/chromosome/cytogenetic analyses, newborn screening tests, HIV viral load testing and resistance testing, tests used to control outbreaks of infectious diseases, tests for low-incidence diseases, and tests that are part of standard recommended care.

Countering Genentech's assertion that existing regulatory oversight is inadequate to ensure that claims made for LDTs are scientifically and clinically proven, ACLA noted that LDTs are subject to both clinical and analytical validation requirements under CLIA (the Clinical Laboratory Improvement Amendments), some state agencies, and the College of American Pathologists. Also, labs that perform genetic tests must meet the most stringent level of CLIA complexity oversight.

ACLA also faulted the assertion that several LDT manufacturers are making claims about their tests related to registered Genentech products without collaboration or consultation with the company—in particular, Herceptin, Rituxan, Avastin, and Tarceva. Review by the FDA or consultation with Genentech are not the sole methods for evaluating clinical and analytical validity claims, ACLA said, noting that in addition to CLIA oversight, there are scientific articles in peer-reviewed journals providing independent review of a competitor's claims about an LDT.

Finally, there is an unresolved legal issue surrounding the FDA's authority to regulate LDTs, ACLA said. ACLA contends the agency lacks jurisdiction because LDTs neither constitute medical devices nor are they distributed commercially in interstate commerce. "Clinical labs that develop and perform LDTs are selling services to outside entities, not identifiable medical devices." The ACLA comprehensive response is posted at *www.clinical-labs.org*, under "What's New."

Use of New Medicare ABN Required March 1

The new ABN (CMS-R-131) replaces three notices previously in use: the general ABN-G, the lab-specific ABN-L, and the Notice of Exclusion from Medicare Benefits (NIR, 29, 21/Sep 15 '08, p. 1).

Medicare will recognize as valid only the revised single-page Advance Beneficiary Notice (ABN), effective March 1, as well as a version tailored to clinical laboratory use (*p. 5*). The ABN must be used to alert Part B fee-for-service beneficiaries when they may be financially liable for an item or service that Medicare is likely to deny. It is never required in emergency or urgent cases.

The lab-customized version differs from the general CMS-R-131 in the layout of the grid to help a beneficiary match a listed or checked testing service, the reasons Medicare may not pay, and the estimated cost of the service. Instead of the headers for these three sections running across the page, the lab version has them stacked in a column running down the left side of the page.

As long as the required language and general formatting of the ABN are not altered, labs may modify the form by preprinting company logos with the name, address, and telephone number (including TTY number when needed) at the top of the notice or by preprinting common reasons for noncoverage (as long as they indicate which portions apply or do not apply to the beneficiary). Also, multiple versions may be specialized for common treatment scenarios. The form should always identify who should be contacted when questions arise. Any changes must be approved by the lab's CMS Regional Office or the lab risks having an invalid ABN and being liable for noncovered charges.

CMS is specific about the ABN's size, print, and look:

- *Length:* The ABN may not exceed one page. Attachments are permitted for additional services; if used, note this in Blank (D).
- *Languages:* CMS-approved ABNs are available only in English and Spanish. Insertions on either must be in the language of the form used. Translation assistance in other languages should be documented in the "Additional Information" section.
- *Print:* Text should be in dark ink on a pale background. No reverse print or block-shaded print.
- *Fonts:* Use the fonts on the CMS-approved form or those that are easily readable, such as Arial, Arial Narrow, Times New Roman, and Courier. Font size for body copy should be 12 point; titles, 14 to 16 point. Insertions in the blanks on the form can be as small as 10 point if needed.
- *Copies:* Have a minimum of two copies—one for the beneficiary, one for the provider. The provider should keep the original wherever possible.
- *Retention:* Keep the ABN for five years from discharge or completion of the delivery of care when there are no other applicable requirements under state law.

What if the beneficiary changes his or her mind after completing an ABN? The provider should have the beneficiary annotate it, indicating the new option selection along with his or her signature and the date. When unable to present the ABN in person, the provider may annotate the form to reflect the beneficiary's new choice and immediately forward a copy to the beneficiary to sign, date, and return. If a related claim has been filed, it should be revised or canceled to reflect the new choice.

What if the beneficiary refuses to choose an option or sign the ABN? The provider should annotate the original, indicating the refusal, and should consider not furnishing the service unless the consequences (the health and safety of the patient or civil liability in case of harm) are such that this is not an option.

Notifier(s):
Patient Name: **Identification Number:**

ADVANCE BENEFICIARY NOTICE OF NONCOVERAGE (ABN)

NOTE: If Medicare doesn't pay for items checked or listed in the box below, you may have to pay. Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the items listed or checked in the box below.

Listed or Checked Items Only:			
Reason Medicare May Not Pay:			
Estimated Cost:			

WHAT YOU NEED TO DO NOW:

- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the checked items listed in the first box above.

Note: If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this.

Options: Check only one box. We cannot choose a box for you.

- ❑ **OPTION 1.** I want the _____listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but **I can appeal to Medicare** by following the directions on the MSN**.** If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.
- ❑ **OPTION 2.** I want the _____listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. **I cannot appeal if Medicare is not billed**.
- ❑ **OPTION 3.** I don't want the _____ listed above. I understand with this choice I am **not responsible for payment,** and I cannot appeal to see if Medicare would pay.

Additional Information:

This notice gives our opinion, not an official Medicare decision. If you have other questions on this notice or Medicare billing, call **1-800-MEDICARE** (1-800-633-4227/**TTY**: 1-877-486-2048).
Signing below means that you have received and understand this notice. You also receive a copy.

Signature:	**Date:**

Form CMS-R-131 (03/08) **Form Approved OMB No. 0938-0566**

Diagnostic Test Claims, *from p. 1*

- ❑ The billing physician or other supplier's actual charge; or
- ❑ The fee schedule amount for the test that would be allowed if the performing supplier billed directly.

The net charge must be determined without regard to any charge that reflects the cost of equipment or space leased to the performing supplier by the billing physician or other supplier.

This anti-markup provision does not apply to independent laboratories, CMS noted.

The Key 'Test'

When the performing physician "shares a practice" with the billing physician or other supplier, the anti-markup provisions do not apply. There are two alternatives for determining whether the "sharing a practice" requirement is met.

— Alternative 1: Substantially All Services

The physician who supervises the technical component (TC) of the test or performs the professional component (PC) furnishes "substantially all" (at least 75 percent) of his or her professional services through the billing physician or other supplier.

— Alternative 2: Site of Service

Only TCs conducted and supervised and PCs performed in the "office of the billing physician or other supplier" by a physician owner, employee, or independent contractor of the billing physician or other supplier will avoid application on the anti-markup rules.

The "office of the billing physician or other supplier" is any medical office space, regardless of the number of locations, in which the ordering physician regularly furnishes patient care. This includes space where the billing physician or other supplier furnishes diagnostic testing, if it is located in the same building where the ordering physician regularly furnishes patient care.

If the billing physician or other supplier is a physician organization, the "office of the billing physician or other supplier" is space in which the ordering physician provides substantially the full range of patient care services that he or she generally provides.

With respect to the TC, the performing supplier is the physician who supervised the TC; with respect to the PC, the performing supplier is the physician who performed the PC.

The anti-markup rules apply to services ordered by physicians, medical groups, and other suppliers regardless of specialty, including pathologists and radiologists who may order diagnostic tests that were not specifically requested by the referring physician, legal analysts point out.

In the Feb. 13 transmittal, CMS also instructed contractors to inform providers about the correct format for billing services subject to anti-markup limits and when electronic and paper claims will be returned as "unprocessable." The transmittal (Change Request 6371) is effective July 1. Contractors are to implement the instructions by July 6. The transmittal is posted at *www.cms.hhs.gov/transmittals*.

♦ Medicare Claims *Advisory*

Revised Codes on the 2009 Medicare Lab Fee Schedule

In addition to the seven new CPT codes covered by the 2009 Medicare Part B laboratory fee schedule (*NIR, Vol. 09, Iss. 01/Jan. 12 '09, p. 4*), there are a number of revised codes that a lab billing department should note. For the revised codes below, the deleted language appears with a strikethrough, while new text is underlined (CPT codes © American Medical Assn.).

Organ or Disease-Oriented Panels

The lists of tests included in the basic metabolic panel (80048), comprehensive metabolic panel (80053), and renal function panel (80069) are revised to clarify that they include <u>total</u> calcium (82310), not ionized calcium. Ionized calcium is included as a component test of a separate basic metabolic panel (80047). Labs are advised to check their requisition forms to clearly differentiate panels 80047 and 80048.

Chemistry

The codes for albumin (82040), potassium (84132), total protein (84155), and sodium (84295) are revised to include plasma and whole blood in addition to serum as specimen sources to accommodate new CLIA waived point-of-care analyzers that utilize whole blood specimens.

Opiates (83925) are now defined as "drug and metabolites, each procedure" to eliminate confusion over how many times the codes can be submitted when multiple opiates or metabolites are determined at the same time.

Former carbon monoxide codes are revised for added clarity and precision:

—82375 ~~Carbon monoxide~~ Carboxyhemoglobin; quantitative

—82376 ~~Carbon monoxide~~ Carboxyhemoglobin; qualitative

Molecular Diagnostics

These CPT codes are revised to clarify the units of service to be reported. Also, the introductory language for this subsection of CPT 2009 notes that each nucleic acid preparation may include a "digestate, undigested nucleic acid, or other uniquely modified nucleic acid sample such as a newly synthesized oligonucleotide."

—83890 Molecular diagnostics; molecular isolation or extraction, <u>each nuclear acid type (ie, DNA or RNA)</u>

—83891 isolation or extraction of highly purified nucleic acid, <u>each nucleic acid type (ie, DNA or RNA)</u>

—83892 enzymatic digestion, <u>each nuclear acid preparation</u>

—83893 dot/slot blot production, <u>each nucleic acid preparation</u>

—83894 separation by gel electrophoresis (eg, agarose, polyacrylamide), <u>each nuclear acid preparation</u>

—83897 nuclear acid transfer (eg, Southern, Northern), <u>each nuclear acid preparation</u>

—83907 lysis of cells prior to nucleic acid extraction (eg, stool specimens, paraffin embedded tissue), <u>each specimen</u>

—83909 separation and identification by high resolution technique (eg, capillary electrophoresis), <u>each nucleic acid preparation</u>

New Medicare Audit Program Ready to Go, With Changes

Four companies have won competitive bids to serve as RACs—Diversified Collection Services, CGI Technologies and Solutions, Connolly Consulting Associates, and Health-DataInsights.

Now that a challenge to the award of contracts under the recovery audit contractor (RAC) program has been settled, the program will go into effect this year nationwide, but with changes to minimize the burden on health care providers, the Centers for Medicare and Medicaid Services announced this month. The RACs will double-check whether Part A and B claims from providers have been overpaid or underpaid (*NIR, 30, 1/Oct 13 '08, p. 3*).

Among the key modifications:

- ❑ The "look-back period" is limited to three years (no farther back than Oct. 7, 2007).
- ❑ RACs will accept imaged medical records from providers on CD/DVDs.
- ❑ RAC requests for medical records are limited. For inpatient claims, it will be 10 percent of average monthly Medicare claims per 45 days, up to a maximum of 200. For physician claims, it will vary by practice size, with larger groups exceeding 16 individuals submitting a maximum 50 medical records per 45 days.
- ❑ To ensure accuracy, each RAC will be required to employ a physician medical director and certified coders; to maximize transparency, new audit issues must be posted to the RAC's Web site.

G-2 Events Calendar

Webinar

March 11: Lab Merger and Acquisition Activity in a Tight Capital Market: How Recent Deals Are Impacting the Industry

Despite financial upheavals in the economy, experts and analysts say the lab and pathology M&A market is healthy and will remain active in 2009. Find out who's buying, who's selling, at what cost, and how it affects the industry

Conferences

June 8-10
Laboratory Outreach 2009: Making Outreach Work: Maximizing Value, Profitability, and Services
Hyatt Regency Mission Bay Spa & Marina
San Diego, Calif.

Sept. 23-25
27th Annual Lab Institute
Crystal Gateway Marriott Hotel
(adjacent to Reagan National Airport)
Arlington, Va.

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