WASHINGTON G–2 REPORTS

NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 32nd Year of Publication

Vol. 11, Iss. 3, February 10, 2011

CMS to Impose Tighter Screening of Providers, Suppliers

The aim, CMS said, is to keep "bad actors" out of these programs by switching from pay-and-chase enforcement to prevention of payment of fraudulent claims.

The Centers for Medicare and Medicaid Services (CMS) has finalized a new rule that tightens the screening requirements for all providers and suppliers enrolling or participating in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP).

The screening measures differ, depending on a provider or supplier's assignment to one of three risk categories: limited, moderate, or high.

Independent clinical laboratories are ranked as moderate fraud risk, subject to unscheduled site visits. CMS noted that "while these labs are subject to surveys under the Clinical Laboratory Improvement Amendments (CLIA), there are nonetheless a number of potentials for fraud, not the least of which is the sheer volume of service and associated billings generated by these entities."

Histocompatibility laboratories and mammography screening centers are ranked as posing limited fraud risk, along with physicians, nonphysician practitioners, medical groups or clinics, and hospitals.

Continued on p. 6

Providers Keep Up a Full Court Press on Physician Signature Policy

A broad range of providers have ratcheted up the pressure on the Centers for Medicare and Medicaid Services (CMS) and on members of Congress over the agency's new policy requiring the signature of a physician or nonphysician practitioner on laboratory test requisitions.

The Clinical Laboratory Coalition has developed a list of 74 questions for CMS on particular concerns involving justification for the new requirements, logistics, impact on patient care, payment issues, education, nursing homes, and dialysis facilities.

On Capitol Hill, a bipartisan Dear Colleague letter reportedly is in the works for CMS, expressing lawmakers' concerns about the policy and its implementation.

CMS has said it will not implement the policy until April 1 to allow time to conduct an education and outreach campaign. However, it is mid-February and CMS has yet to release further guidance, critics note. CMS officials say they are reviewing the policy in light of issues they had not considered but were brought to their attention by providers. Staff are working on a series of frequently asked questions (FAQs) to explain the policy.

INSIDE *NIR*

CMS gears up for new lab test payment demonstration 2

New pathology measures under review for 2012 physician quality reporting program..... 3

Can you rely on CMS guidance as a legal defense? 4

President renominates Berwick as CMS administrator 5

Chart: Three-tiered model for tighter screening of providers..... 6

Upcoming G-2 Events..... 8

Webinars

- ❒ Feb. 17, CLIA compliance
- ❒ Feb. 23, Disaster preparedness

Conferences

- ❒ April 13-15, Molecular Diagnostics
- ❒ June 15-17, Lab Outreach 2011

www.g2reports.com

CMS Gears Up for Lab Test Payment Demo

The planned pilot project is narrower in focus than what its proponents sought. CMS includes only tests that ordinarily would be bundled into the hospital's inpatient Medicare payment and excludes tests ordered after an outpatient encounter, saying these are already separately payable under the Part B clinical lab fee schedule.

The Centers for Medicare and Medicaid Services (CMS) has alerted local contractors to the scheduled summer startup of a new Medicare demonstration project to pay clinical laboratories directly for certain complex diagnostic tests ordered within 14 days of a beneficiary's hospital discharge.

Under the current "date of service" rule, tests ordered within the 14-day window are considered reimbursed under the hospital's prospective payment and the lab must seek payment from the hospital, not Part B.

The project is slated to begin July 1, 2011, and run for two years or until a $100 million payment ceiling has been reached, CMS announced in Transmittal 2144 (Jan. 28, 2011). The demonstration is required under Section 3113 of the health care reform law (the Patient Protection and Affordable Care Act).

Participation in the pilot project is open to all hospital-based and independent clinical labs. They will be paid directly under a separate fee schedule that CMS will establish to pay for covered tests. There will be no locality variation on this fee schedule. Payment amounts will be national amounts.

Complex Tests Defined

For purposes of the demonstration, a "complex diagnostic laboratory test" is:

- ❏ an analysis of gene protein expression, topographic genotyping, or a cancer chemotherapy sensitivity assay;
- ❏ determined by the secretary of health and human services to be a laboratory test for which there is no alternative test having equivalent performance characteristics;
- ❏ billed using a Health Care Procedure Coding System (HCPCS) code other than a "not otherwise classified" code;
- ❏ approved or cleared by the Food and Drug Administration or covered under Title XVIII of the Social Security Act; and
- ❏ described in Section 1861(s)(3) of the act (42 U.S.C. 1395x(s)(3)).

Billing Modifier for Claims

HCPCS codes included in the demonstration are to be billed with the project identifier 56. By submitting a claim with this identifier, the laboratory agrees to cooperate with the independent contractors selected by CMS to run and evaluate the demonstration. This may include providing data to assess the impact of the pilot project and taking part in surveys or site visits as requested by the contractors.

Laboratories are to report the identifier 56 in item 19 on the CMS 1500 form, in locator 63 on the UB04, on the electronic claim in X12N 837P (HIPAA version) Loop 2300, REF02, REF01=P4, and in X12N 837I (HIPAA version) Loop 2300, REF02, G1 in REF01 DE 128.

Tracking Payments

The project will develop a report to track contractors and laboratories participating in the demonstration, daily volume, and amount paid as well as cumulative

Continued on p. 7

Physician Quality Reporting: Five New Pathology Measures Under Review for 2012

Five pathology measures developed by the College of American Pathologists (CAP) are being reviewed at the Centers for Medicare and Medicaid Services for inclusion in the 2012 Physician Quality Reporting System, reports CAP's Feb. 3 *Statline*. And the National Quality Foundation has been notified that the measures are ready for its endorsement process.

The measures were forwarded following approval by the American Medical Association's Physician Consortium for Performance Improvement. They include:

Barrett's Esophagus
Esophageal biopsies with a diagnosis of Barrett's esophagus that also include a statement on dysplasia.

Radical Prostatectomy Pathology Reporting
Reports include the pT category, the pN category, the Gleason score, and a statement about margin status.

Cytopathology
Turnaround time (TAT) for routine nongynecologic cytopathology specimens.

Immunohistochemical (IHC) Evaluation of HER2 for Breast Cancer Patients
Quantitative HER2 evaluation by IHC uses the system recommended by the American Society of Clinical Oncology-CAP guidelines.

Bone Marrow and FNA/Direct Specimen Acquisition
Bone Marrow and Fine Needle Aspiration (FNA)/Direct Specimen Acquisition timeout procedure.

The measures were developed, *Statline* reported, under the auspices of the Public Health Policy Committee by the CAP Measures Development Workgroup, the Cytopathology Committee, and the Molecular Oncology Committee, with input from the American Urological Association.

In 2011, pathologists and other eligible Part B providers are entitled to an incentive payment of 1 percent of total allowed charges for successfully reporting on quality measures. Currently approved pathology measures are:

- ❏ Breast cancer resection pathology reporting: pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade.
- ❏ Colorectal cancer resection pathology reporting: pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade.

The Patient Protection and Affordable Care Act authorized the incentive payment program through 2014 and established a penalty for providers who do not report quality measures beginning in 2015. The law also provides an additional 0.5 percent bonus in 2011 for physicians who qualify for a continuous assessment program (the Maintenance of Certification Program, MOCP) as well as a subsequent penalty for those who do not meet the standards in the future. But as *Statline* noted, current pathology MOCP requirements do not meet the criteria for a qualifying MOCP.

Can You Rely on CMS Guidance as a Legal Defense?

You should be able to, argues the American Hospital Association (AHA) in an amicus brief filed in support of a South Carolina hospital facing repayment of $45 million for improper payments resulting from violation of the Stark restrictions on physician self-referrals. Tuomey Healthcare System is appealing a lower court judgment ordering it to repay the money.

The Stark law prohibits a physician (or immediate family member) from referring Medicare and Medicaid patients to facilities with which the physician (or an immediate family member) has a financial relationship by ownership interest or compensation arrangements or both. The law is broad but allows numerous exceptions.

In the lower court case, Michael Drakeford, an orthopedic surgeon that Tuomey tried to hire, alleged that Tuomey entered into improper compensation agreements with physicians that exceeded fair market value and were based on the volume of patient referrals. The trial jury returned a split verdict, upholding the Stark allegations but dismissing false claims allegations, thus significantly reducing the amount of repayment.

Taking CMS at Its Word

In its brief filed with the U.S. Court of Appeals for the Fourth Circuit, AHA said, "The Department of Justice dismissed the rights of hospitals to rely on the Centers for Medicare and Medicaid Services' commentary when trying to make business decisions that would be compliant with the Stark law. [This] is of great concern to AHA, hospital management, hospital boards of directors, and hospital counsel across the country."

The complexity of the Stark law, the brief said, makes reliance on official CMS guidance an imperative. "In deciding this case, the court should confirm that hospitals can rely on CMS guidance when making business and health care policy decisions without worrying that the Department of Justice or a qui tam relator (whistleblower) will come in after the fact and disavow conduct that CMS has clarified is consistent with the Stark law." The brief also faulted the government for not providing an accurate accounting of the total payments it made to Tuomey for the allegedly improper referrals.

Implications of the Case

Asked by *NIR* for comment on the legal proceedings, health law attorney Robert Mazer with Ober/Kaler in Baltimore replied in an e-mail:

"From a practical perspective, there may be a single issue—the extent to which a health care provider can rely on CMS commentary as to the meaning of the related regulations. This is an important issue because the commentary in a final rule is frequently easier to understand than the language of the regulation itself.

"From a legal perspective, there are at least two issues. First, the relevance and weight properly given to statements in the preamble to a final rule. Second, the ability to avoid sanctions based on reliance on such statements.

"As to the first issue, courts frequently give significant weight to statements in the preamble of a final rule as to the meaning and application of the related regulations. Unless there was a clear conflict between the actual language of the regulation and

the related commentary, I would expect a court to be reluctant to accept an interpretation that was at odds with the preamble language.

"Second, in most respects, the Stark law is a strict liability law. That means that if a hospital or laboratory received Medicare payments for services that resulted from a referral from a physician with which it had a prohibited financial relationship, it can be required to return the payments—even if it did not know that the financial relationship was impermissible.

"But the issue is more complicated when the government seeks to impose fines or penalties in addition to recovering the Medicare payments. Depending upon its particular legal theory, the government may have to prove that the hospital or laboratory knew that the arrangement with the physician was impermissible, should have known that it was impermissible, or acted with reckless disregard as to whether or not it was permissible. If the hospital or laboratory could demonstrate that it reasonably relied on statements in the preamble showing that the arrangement complied with legal or regulatory requirements, that might prove to be a valid defense against a claim for fines or penalties."

President Renominates Berwick as Head of CMS

President Obama Jan. 26 renominated Donald M. Berwick, M.D., as administrator of the Centers for Medicare and Medicaid Services (CMS). The post of permanent administrator, vacant since 2006, requires Senate confirmation. No date has been set for hearings before the Finance Committee, said chairman Max Baucus (D-Mont.), noting that the panel has yet to lay out its schedule for 2011.

Berwick is currently serving as head of CMS under a recess appointment made by Obama in July 2010, allowing him to serve through 2011 without Senate confirmation. Such appointments can be made only when Congress is not in session. He was nominated to lead CMS in April 2010 but drew strong opposition from Republicans on the Finance panel, though a wide range of health care stakeholders, including leading hospital groups, endorsed him.

Berwick would not comment on whether he expected a rocky confirmation process, saying only that he is enjoying the job he is doing—running the agency.

Tough Questioning Expected

Berwick is likely to be grilled by Republicans on the Finance panel and on the Senate floor if the nomination is considered. They have been critical of comments they say he has made favoring the British national health care system and rationing of health care.

Industry sources say the White House regards him as an able agency leader and that losing him at the end of the year and finding a replacement in 2012, an election year, would be disruptive for the agency as it moves ahead with implementing the health care reform law.

Berwick, a pediatrician, is a clinical professor of pediatrics and health care policy at the Harvard Medical School and the Harvard School of Public Health. He also is president and chief executive officer of the Institute for Healthcare Improvement, a nonprofit organization (based in Cambridge, Mass.) that promotes the improvement of health care.

CMS to Impose Tighter Screening of Providers, *from p. 1*

Newly enrolling home health agencies and suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) are assigned to the category of high fraud risk, subject to fingerprinting and criminal background checks as well as unscheduled site visits.

The final rule, published in the Feb. 2 *Federal Register* and effective March 25, applies to all providers and suppliers in the above federal health care programs, including those newly enrolled on March 23 and those currently enrolled and revalidating their status as of March 25.

The rule implements provisions in the Patient Protection and Affordable Care Act (PPACA), giving the secretary of health and human services new discretionary authority to increase the level of screening for providers and suppliers operating within federal health care programs.

A new fee would be imposed on institutional providers to pay for the tougher screening rules. Initially, the fee is $500, to be updated by the consumer price index update. It does not apply to Part B medical groups or clinics, physicians, and nonphysician practitioners submitting a CMS application for enrollment in Medicare.

Three-Tiered Model for Tighter Screening

RISK LEVEL	*PROVIDER OR SUPPLIER CATEGORY*	*SCREENING CHECKS*
Limited	Physician or nonphysician practitioners and medical groups or clinics (with the exception of physical therapists and physical therapist groups). Ambulatory surgical centers, competitive acquisition program/ Part B vendors, end-stage renal disease facilities, federally qualified health centers, histocompatibility laboratories, hospitals, including critical access hospitals, Indian Health Service facilities, mammography screening centers, mass immunization roster billers, organ procurement organizations, pharmacies newly enrolling or revalidating via the CMS-855B, radiation therapy centers, religious nonmedical health care institutions, rural health clinics, and skilled nursing facilities.	Verify any provider or supplier requirements set forth by Medicare; verify his or her licensing; and undergo database checks before and after enrollment to verify Social Security numbers, tax delinquency, and any exclusions by the Office of Inspector General.
Moderate	Ambulance suppliers, community mental health centers; comprehensive outpatient rehabilitation facilities; hospice organizations; independent diagnostic testing facilities; independent clinical laboratories; physical therapy, including physical therapy groups and portable X-ray suppliers; currently enrolled (revalidating home health agencies).	Same as limited risk level, plus unscheduled site visits.
High	Prospective (newly enrolling) home health agencies and prospective (newly enrolling) suppliers of durable medical equipment, prosthetics, orthotics, and suppliers (DMEPOS).	Same as limited and moderate risk, plus criminal background checks and fingerprint checks.

New Screening Rule at a Glance

❑ Creates a rigorous screening process for providers and suppliers enrolling in Medicare, Medicaid, and CHIP to keep fraudulent providers out of those programs. Types of providers and suppliers identified in the past as posing a higher risk of fraud, for example durable medical equipment suppliers, will be subject to more thorough screening.

- ❏ Requires new enrollment process for Medicaid and CHIP providers. States will have to screen providers who order and refer to Medicaid beneficiaries to determine if they have a history of defrauding government. Providers kicked out of Medicare or another state's Medicaid or CHIP will be barred from all Medicaid and CHIP programs.
- ❏ Temporarily stops enrollment of new providers and suppliers. Medicare and state agencies will be on the lookout for trends that may indicate fraud, including using advanced predictive modeling software, such as that used to detect credit card fraud. If a trend is identified in a category of providers or geographic area, the program can temporarily stop enrollment as long as that will not impact access to care for patients.
- ❏ Temporarily stops payments in cases of suspected fraud. If there has been a credible fraud allegation, payments can be suspended while an action or investigation is under way.

CMS Gears Up for Lab Test Demo, *from p. 2*

volume and amount paid during the demonstration period. Total payments under the project may not exceed $100 million.

Report to Congress

Within two years after completion of the demonstration, HHS is to report to Congress on its impact on access, quality, health outcomes, and expenditures.

Background of the Demo

Congress authorized the new demonstration after lobbying by lab industry groups that have long chafed under Medicare's "date of service" rule. If a lab performs a test on a blood or tissue sample collected by the hospital for inpatients and outpatients, but within 14 days of the beneficiary's discharge, it must be paid by the hospital. Only tests ordered after the 14 days are separately billable to Part B.

In its critique of the rule, the American Clinical Laboratory Association (ACLA) has noted that it is not unusual "for a physician to order follow-up testing on a blood or tissue sample after a patient has left the hospital, but before 14 days. These tests are performed by specialty labs that could be hundreds of miles away from the hospital. So, the hospital may be reluctant or unwilling to pay for a test it did not order and perform for a patient it is no longer caring for. The hospital also may not be familiar with the test or why it was ordered."

Waiting until after the 14-day period to order diagnostic tests jeopardizes timely access to advanced technologies for patients who may be facing a critical illness—for example, tests to determine the source of a cancer and what types of treatment may be most effective.

The rule further undermines the development of new medical technologies, especially personalized medicine, if the companies involved cannot be assured of payment for medically necessary tests, ACLA said.

The solution, ACLA concluded, is to enable labs to bill Medicare directly for tests ordered after an inpatient stay or outpatient visit, eliminating the hospital as the middleman. CMS, however, has limited the demonstration to tests that otherwise would be bundled into the Medicare payment for an associated hospital inpatient stay.

• Upcoming G-2 Events •

Webinar *2 p.m. – 3:30 p.m. (Eastern)*

Feb. 17

Keeping Ahead of the Curve: CLIA Compliance 2011

Feb. 23

Planning for the Unexpected: Disaster Preparedness for Labs

Conferences

April 13-15

Molecular Diagnostics Spring 2011: MDx Goes Mainstream
Fairmont Copley Plaza
Boston

June 15-17

Laboratory Outreach 2011
Caesars Palace
Las Vegas

For details and registration savings, go to www.g2reports.com

NIR Subscription Order or Renewal Form

❑ ***YES***, enter my one-year (22-issues) subscription to the *National Intelligence Report (NIR)* at the rate of $509/yr. Subscription includes the *NIR* newsletter and electronic access to the current and all back issues at *http://www.g2reports/issues/NIR*. Subscribers outside the U.S. add $100 postal.*

❑ AAB & NILA members qualify for special discount of 25% off — or $381.75 (Offer code NIRI1).

❑ I would like to save $204 with a 2-year subscription to *NIR* for $814.*

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_____

Mail to: Washington G-2 Reports, 1 Phoenix Mill Lane, Fl. 3, Peterborough, NH 03458-1467 USA. Or call 973-718-4700 and order via credit card or fax order to 973-718-0595

*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. For multi-subscriber distribution within a company or for permission to republish, please contact IOMA's corporate licensing department at 973-718-4703, or e-mail jping@ioma.com. NIR 2/11A

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 Phoenix Mill Lane, Fl. 3, Peterborough, NH 03458-1467 USA. Telephone: (973) 718-4700. Fax: (973) 718-0595. Web site: www.g2reports.com.

Jim Curren, Editor; Dennis Weissman, Executive Editor; Heather Lancey, Designer; Beth Butler, Marketing Director; Dan Houder, CMO; Doug Anderson, VP & 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.