G2 INTELLIGENCE

NATIONAL INTELLIGENCE REPORT™

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 35th Year of Publication

Vol. 14, Iss. 3, February 6, 2014

INSIDE *NIR*

www.G2Intelligence.com

Labs Have Six Months to Comply With Patient Access Rule

Clinical laboratories will have six months to comply with a new rule from the Department of Health and Human Services (HHS) requiring them to provide patients or their representative copies of completed test reports within 30 days of a request being filed.

The final rule, announced Feb. 3 and published in the Feb. 6, 2014, *Federal Register*, amends the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to allow individuals to access test reports directly from laboratories. The rule finalizes a proposal issued Sept. 14, 2011.

The rule becomes effective 60 days after publication, and labs must comply 180 days after that, so labs essentially have 240 days (eight months) from the publication date to come into compliance.

Currently, nine states and territories already allow patients to access test results directly from labs: Delaware, the District of Columbia,

Continued on p. 2

ACOs Off to Strong Start, Says CMS; 29 Groups Will Share $126 Million

Some accountable care organizations (ACOs) are achieving their goal of saving Medicare money while improving the quality of care they offer, the Centers for Medicare and Medicaid Services (CMS) said Jan. 30.

In its first report on the operation of Medicare's ACO program, CMS said the entities shared in $273 million of savings in 2012 and funneled an additional $128 million to the Medicare trust fund.

In a statement, the agency said interim financial results for the Medicare Shared Savings Program (MSSP) ACOs show that in their first 12 months, nearly half (54 out of 114) of the ACOs that started operations in 2012 already had lower expenditures than projected.

Of the 54 ACOs that exceeded their benchmarks in the first 12 months, 29 generated shared savings totaling more than $126 million, the agency said.

Under the program, ACOs that meet certain targets can share in savings. Thus, the 29 ACOs will share in the $126 million in savings they generated. The agency also said Pioneer ACOs "generated gross savings of $147 million in their first year while continuing to deliver high quality care."

Continued on p. 6

Labs Have Six Months to Comply With Patient Access Rule, *from p. 1*

Maryland, New Hampshire, New Jersey, Nevada, Oregon, Puerto Rico, and West Virginia. Other states either allow test reports only to providers, allow test results to patients with provider approval, or have no state law addressing access. The final rule pre-empts all state laws on this issue. The Centers for Medicare and Medicaid Services (CMS) estimates that almost 23,000 labs performing more than 7 billion tests will be affected by these new provisions.

The final rule adopts many of the changes proposed in 2011 with some minor clarifications and conforming changes. According to CMS, these changes broaden individuals' rights to access their protected health information directly from laboratories subject to HIPAA. In addition, the changes remove federal barriers to direct access for laboratories not subject to HIPAA.

CMS notes that the right to access health information extends to test reports created before the publication or effective date of the final rule.

In releasing the rule, HHS Secretary Kathleen Sebelius says that it is part of ongoing efforts to empower patients to be informed partners with their health care providers. While individuals already have a right of access to their health information under the HIPAA privacy rule, there may be circumstances when an ordering or treating provider is not subject to the HIPAA privacy rule (i.e., because the provider does not bill health plans electronically) and thus is not required to provide an individual with access to his or her health information.

According to CMS, some studies have found that physician practices failed to inform patients of abnormal test results about 7 percent of the time, resulting in a substantial number of patients not being informed by their providers of clinically significant test results.

The rule does not alter the role of the ordering or treating provider in reporting and explaining test results to patients. CMS says it expects that patients will continue to obtain test results and advice about what those test results mean through their ordering or treating providers. In the final rule, CMS responds to comments raised in response to the proposed rule. Among some of the more significant:

- **Reference Labs.** Some commenters suggested that the rule apply only to the primary lab to which the specimen was submitted since reference laboratories have no relationship with the individual. CMS disagrees, saying that applying the access requirements as broadly and uniformly as possible best furthers the goal of increasing direct individual access rights to health information.
- **Old Test Reports.** Commenters expressed concern about labs having to retrieve copies of old test reports that have been archived and may exist offsite. CMS notes that the right to access health information extends to test reports created before the publication or effective date of the final rule. The rule does not impose any new record retention requirements for laboratory test reports.
- **30-Day Time Frame.** CMS believes that 30 days should be sufficient for a lab to provide access to completed test reports. However, in those limited cases where 30 days may not be sufficient due to the nature of the test being performed, the lab should explain to the patient that the report will take longer than 30 days to obtain. The patient could then withdraw or hold the request until a later time. If an individual chooses not to withdraw the request, the individual will then only have a right to obtain the protected health information in the designated record set at the time the request is fulfilled, which may not include a particular test report because it is not yet complete. If a lab determines after it has accepted a request that the test will take more than 30 days to analyze and complete, it may notify the individual

in writing within the initial 30-day period of the need and specific reason for the delay. The HIPAA privacy rule allows only one extension on an access request.

- **Sensitive Tests.** Some labs objected to individuals having direct access to lab test reports that that are "sensitive," such as genetic, cancer, pregnancy, sexually transmitted diseases, and mental health test results. Under California law, for example, before the disclosure of HIV test results, the physician has a duty to discuss what the results may mean and offer the patient appropriate education and psychological counseling. CMS says that with a very limited exception, covered entities may not deny an individual access to health information based on the information's sensitive nature or potential for causing distress. The limited exception is for cases where a licensed health care professional has determined that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person, and the individual is provided a right to have the denial of access reviewed by an unaffiliated health care professional.

- **Food and Environmental Tests.** The final rule applies to test reports maintained by labs subject to or exempt from CLIA. If the samples tested are not of the human body, the entity conducting the testing is not subject to CLIA for purposes of that testing or those test results. If the testing is not for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings, that testing and those test results are also not subject to CLIA.

- **Substance-Abuse Testing.** CLIA regulations are not applicable to an employer or entity that performs substance abuse testing strictly for the purpose of employment screening, as opposed to some form of treatment. Substance abuse testing as part of a treatment program is covered by CLIA.

- **Access by Personal Representatives.** The only persons who have a right to access an individual's test reports directly from a HIPAA-covered entity are those who qualify as a personal representative of the individual. Before providing access to a person other than the patient, a HIPAA-covered laboratory is required to verify both the identity and authority of the person to have access. This means a lab may need to have the person present a written health care power of attorney, general power of attorney, or durable power of attorney.

CMS says that with a very limited exception, covered entities may not deny an individual access to health information based on the information's sensitive nature or potential for causing distress.

- **Fees.** HIPAA-covered laboratories must comply with the same fee limitations specified in the privacy rule. This means a covered lab may charge an individual a reasonable, cost-based fee that includes only the cost of (1) labor for copying the protected health information requested, whether in paper or electronic form; (2) supplies for creating the paper copy or electronic media if the individual requests that the electronic copy be provided on portable media; (3) postage, when the individual has requested the copy be mailed; and (4) preparation of an explanation or summary of the protected health information.

- **Cost.** CMS estimates it will take labs two to nine hours to identify the applicable legal obligations and develop the process and procedures for handling patient requests, at a cost of about $100 to $450. It estimates a range of 10 to 30 minutes to handle a request from start to finish, at a cost of about $10 to $30 per request. Total cost on a national level across all labs is estimated at about $63 million.

Takeaway: Laboratories should begin now to establish policies and procedures for responding to patient requests for copies of test resports.

focus on: Hospital Outpatient Bundling

What Effect Will Outpatient Bundling Have on Hospital Labs? Verdict Still Out, but Executives Urged to Take Steps Now

While it's still not entirely clear just how hospitals will be affected by new bundling regulations now in effect under Medicare, one thing is certain: Hospitals need to get a head start on estimating the impact and apportioning lab charges so they can effectively evaluate labs' financial performance and budget intelligently for the coming year.

Initial concerns that the bundling rule, finalized Dec. 10, 2013, would eliminate reimbursement for outpatient lab tests appear to be unfounded, says Barry Portugal, president, Health Care Development Services Inc. (HCDS; Nokomis, Fla.). HCDS is a management consulting firm to hospitals and hospital laboratories. However, hospital executives will need to do some extra work to figure out just how lab reimbursement should be allocated appropriately, and hospital lab executives may need to perform some lab-specific analysis.

Under the bundling rule, five outpatient/clinic ambulatory payment classifications (APCs) are collapsed into one (APC 0634), and laboratory tests associated with a Medicare primary service visit will be bundled into this APC. As a result, hospitals will no longer be paid separately for those services. APC 0634 (Hospital Clinic Visits) will be reimbursed at $92.53 in 2014.

Bundling Policy Laboratory Specific Impact by Bed Size, Rural Hospitals (2013-2014)

NUMBER OF BEDS	NUMBER OF HOSPITALS	RECALIBRATION SPECIFIC TO OUTPATIENT LABORATORY PACKAGING (%)
0-49	363	-2.50
50-100	346	-1.10
101-149	133	-0.20
150-199	60	-0.60
200+	44	+0.40

Source: CMS Hospital Outpatient Prospective Payment System Rule, Dec. 10, 2013

Bundling Policy Laboratory Specific Impact by Bed Size, Urban Hospitals (2013-2014)

NUMBER OF BEDS	NUMBER OF HOSPITALS	RECALIBRATION SPECIFIC TO OUTPATIENT LABORATORY PACKAGING (%)
0-99	1037	+0.4
100-199	843	+0.2
200-299	458	+0.3
300-499	410	+0.3
>500	211	-0.2

Source: CMS Hospital Outpatient Prospective Payment System Rule, Dec. 10, 2013

To be bundled, the lab tests would have to be provided on the same date of service as the primary service and ordered by the same practitioner who ordered the primary service. Molecular pathology tests and bypass tests are exempt from this bundling policy.

According to the Centers for Medicare and Medicaid Services (CMS), additional money will be allocated to APC 0634 to account for the bundling policy. How hospitals are affected largely will depend on the type and size of hospital and the number of outpatient tests they perform. Rural hospitals and major teaching hospitals are likely to see the greatest reimbursement decrease, while nonteaching hospitals could actually see a slight increase in Medicare reimbursement as a result of the bundling regulations. Small rural hospitals could see Medicare reimbursement cuts to laboratory outpatient services of up to 2.5 percent.

Bundling Payment Policy

Under the new policy that took effect Jan. 1, 2014, a laboratory test performed on a Medicare outpatient will be separately paid when it is the only service provided to a beneficiary on that date of service or the lab test is the same date of service as the primary service but is ordered for a different purpose than the primary service by a practitioner different than the practitioner who ordered the primary service.

When a lab test is the only service provided to a beneficiary at the hospital, the hospital can receive separate payment for those lab tests by billing for these services on a 14x claim. Medicare will pay hospitals for those services based on the Clinical Laboratory Fee Schedule payment rate.

The problem, says Portugal, is not that hospitals won't be paid for Medicare laboratory testing performed in outpatient settings; it's that some hospitals may gain modest reimbursement while others may lose some Medicare reimbursement. More importantly, Portugal notes that under the bundling regs, there is no way to allocate the Medicare laboratory charges to the laboratory cost center; thus, laboratory charges will not be appropriately apportioned back to the lab. Without having this information, hospital and laboratory executives will be unable to effectively evaluate the lab's financial performance and to intelligently budget for the coming year.

Calculate Impact Now

Because Medicare outpatient test volume, mix, and cost-to-charge ratio varies dramatically from one hospital to the next and the proportion of Medicare outpatient tests associated with a primary service differs between hospital type, the only way for hospitals and hospital labs to truly know how the bundling proposal will impact the organization's bottom line is to perform an impact analysis specific to their hospital, says Portugal.

He advises that hospitals follow a four-step process to estimate the impact of the bundling policy on Medicare outpatient laboratory charges:

1. Define historical baseline of Medicare outpatient lab charges associated with primary services;
2. Identify what percentage of first-quarter 2014 APC 0634 charges are laboratory specific;
3. Compare baseline total Medicare outpatient primary service charges to first-quarter actual; and
4. Track differences over time and reapportion charges from APC 0634 back to laboratory cost centers.

"Hospital leaders need to know how to reapportion charges so they can appropriately budget for capital expenses," says Portugal. "Sooner rather than later, they will need to figure this out."

Hospital Groups Reviewing Models

The American Hospital Association, the American Association of Medical Colleges, and the Federation of American Hospitals have commissioned an analysis to determine if CMS modeling of the impact of the bundling policy is correct. While it's not entirely certain when that analysis will be completed, when the report is available, it may provide the basis to a challenge of the bundling regulations.

"Until challenges are considered, APC payment mechanisms now in place will drive reimbursement for outpatient Medicare services," notes Portugal.

Takeaway: Hospital leaders need to work with hospital executives to determine how to appropriately allocate lab revenues under Medicare's new primary care bundling policy.

ACOs Off to Strong Start, Says CMS, *from p. 1*

"Results showed that of the 23 Pioneer ACOs, nine had significantly lower spending growth relative to Medicare fee for service while exceeding quality reporting requirements. These savings far exceed findings from a previous analysis conducted by CMS, which used a different methodology," CMS said.

The Pioneer program is administered under CMS's Center for Medicare and Medicaid Innovation and is designed for health-care organizations and providers that have experience coordinating care for patients across care settings. The program allows those provider groups to move more rapidly from a shared savings payment model to a population-based payment model on a track consistent with, but separate from, the MSSP.

Thirty-two Pioneer ACOs participated in the first year of the program, yet only 13 performed well enough against cost benchmarks to share in savings for the program. After the first year, seven of the Pioneers decided to transition to the "traditional" MSSP, while two left the program entirely.

Accountable care organizations "are designed to achieve savings over several years, not always on an annual basis, but this is a very strong start," said CMS.

Thirty-two Pioneer ACOs participated in the first year of the program, yet only 13 performed well enough against cost benchmarks to share in savings for the program.

ACOs aim to improve the quality and lower the cost of health care through several mechanisms, such as disease management programs, care coordination, and the alignment of financial incentives for hospitals and physicians.

The Affordable Care Act created the MSSP for such entities. About 250 Medicare ACOs were established under the MSSP prior to 2014, and about half are physician-run. The initial terms of the ACO contracts were required to be at least three years, according to CMS. The agency in December announced the addition of 123 new ACOs, with a performance period that began Jan. 1.

CMS says ACOs now serve 5.3 million beneficiaries, or about 12 percent of the Medicare population.

Quality Improvements

The agency didn't release information on the quality of care being offered by ACOs, but CMS Principal Deputy Administrator Jonathan Blum told reporters on a telephone conference call that ACOs "are doing better with quality metrics" than many other providers.

Blum said he expects ACOs will continue to improve in the coming years, generating more savings for themselves and Medicare. ACOs that didn't perform well enough to share in savings likely will improve their performance by making changes in how they deliver care, including experimenting with new staffing models as well as making other investments, he added.

"We're in this for the long term," Blum said. "But what is impressive is the first-year results."

The agency plans to release information on the individual performance of ACOs and their quality metrics at a future date, Blum said. Final results on the first year of the program will be released later this year, CMS said.

Takeaway: ACOs are already generating cost savings for the Medicare program, which means they are likely to continue growing. Labs should make sure they have a seat at the ACO table before they are shut out of shared savings.

January Update of CLIA-Waived Tests, Billing Codes

The Jan. 10, 2014, update to the list of tests waived under the Clinical Laboratory Improvement Amendments (CLIA) includes six new tests approved by the Food and Drug Administration.

CPT CODE	EFFECTIVE DATE	DESCRIPTION
G0434QW	May 29, 2013	SCI International Inc. New Choice at Home Drug Test: Marijuana (strip format)
82465QW, 83718QW, 84478QW, 82962	July 1, 2013	Infopia USA LipidPro Professional Lipid Profile and Glucose Measuring System
G0434QW	July 29, 2013	Alere iCup DX 14 (Cassette Dip Card Format)
G0434QW	Sept. 25, 2013	American Screening Corp. Inc. Discover Drug Test Cards
G0434QW	Sept. 25, 2013	American Screening Corp. Inc. Discover Multi-Panel Drug Test Cups
82465QW, 83718QW, 84478QW, 82962	Nov. 12, 2013	Jant Pharmacal Corp., LipidPlus Professional Lipid Profile and Glucose Measuring System

When billing for the tests below, you must use the QW modifier. This enables your local Medicare contractor to recognize the code as waived.

The January update, plus a complete list of CLIA-waived tests and devices, can be found in Transmittal 2854 (Change Request 8560) at *www.cms.gov* under "Transmittals." The implementation date is April 7, 2014.

April NCD Edit Module Will Include ICD-10 Codes

ICD-10 translations for all the ICD-9 codes in the 23 laboratory national coverage decisions (NCDs) will be included in the April quarterly release of the NCD edit modules for laboratory services, according to the Centers for Medicare and Medicaid Services (CMS).

According to transmittal R2852CP (Change Request 8585), released Jan. 10, the ICD-9 code changes will be effective on April 1, while labs will have until Oct. 1 to get the ICD-10 codes entered into their software for editing claims for medical necessity and advance beneficiary notice checks.

CMS is required to update the laboratory NCD edit modules quarterly in accordance with Chapter 16, §120.2 of CMS Internet Only Claims Processing Manual (Pub. 100-04). These updates are part of the routine maintenance of the NCDs and are usually ministerial changes like adding new codes, deleting codes, and accommodating biannual changes to the ICD-9 codes. Aside from the inclusion of the ICD-10 codes, there were no other changes to the NCDs noted in the transmittal.

Medicare *Claims Advisory*

Interest Rate Increases for Overpayment, Underpayment

The rate of interest that Medicare will pay you for claims that were underpaid, or collect from you from claims that were overpaid, has increased to 10.25 percent, up from the 10.125 percent that has been in effect since Oct. 18, 2013. The change is effective as of Jan. 21, 2014.

The Centers for Medicare and Medicaid Services (CMS) announced the latest update in Transmittal 230, Change Request 8624. Medicare Regulation 42 CFR 405.378 provides for the assessment of interest at the higher of the current value of funds rate (1 percent for calendar year 2014) or the private consumer rate as fixed by the Department of the Treasury.

The highest interest rate in the past decade was in early 2001, when it was 14.125 percent, but for most of the years since, the rate has hovered between 10.5 percent and 12 percent.

Pathology Groups Make Recommendations on Workforce Issues

Groups representing pathologists this week issued recommendations to help pathologists best meet patient needs in the future.

The report is the outcome of the December 2013 Pathology Workforce Summit, sponsored by the College of American Pathologists (CAP), the American Society for Clinical Pathology, the Association of Pathology Chairs, and the United States and Canadian Academy of Pathology.

The summit identified five emerging issues that will impact the pathology workforce:

- ❑ **A decreased supply of pathologists and laboratory professionals.** The supply of pathologists and lab professionals will decrease substantially over the next 20 years.
- ❑ **Changes in the demand for pathology services.** The demand for pathology and lab services over the next 10 to 20 years will be affected by changes in population age and disease incidence.
- ❑ **New factors requiring creative reconsideration of the nature of recruitment and training and advocacy for adequate resources.** The number of new pathologists expected to graduate in the next 15 years is far below the number of pathologists expected to leave practice, and current approaches for training pathologists may not be addressing the changing needs for pathology practice.
- ❑ **Workforce projections that must account for all members of the laboratory team.** Laboratory professionals' roles tend to be technically distinct and complementary, as opposed to being subsets, and therefore projections must account for each distinct need or member of the care team.
- ❑ **Access to education and training opportunities.** The availability of training programs will be critical in maintaining and developing an adequate supply of qualified pathologists and laboratory professionals.

In response to these issues, participants agreed on three key recommendations to address future workforce issues:

1 Reassessing what every pathologist needs to know and identifying new ways to ensure that adequate numbers of pathologists acquire both general skills and subspecialized expertise, especially in key emerging areas;

2 Organizing pathology to attract and recruit highly qualified medical and STEM (science, technology, engineering, and mathematics) students into pathology and laboratory professions; and

3 Re-evaluating long-term training expectations to propagate an outlook of lifelong learning to maintain or enhance career opportunities and applicability to current health care delivery systems and payment models.

Takeaway: Pathology and laboratory medicine must face and address a potential shortage of professionals expected over the next 20 years.

 National Intelligence Report (ISSN 2332-1458) is published by G2 Intelligence, 24 Railroad Street, Keene NH 03431-3744 USA. Tel: 800-531-1026 or +1 603-357-8101. Fax: +1 603-357-8111. Web site: www.G2Intelligence.com.

Kimberly Scott, Managing Editor, kscott@G2Intelligence.com; Heather Lancey, Designer; Beth Butler, Marketing Director; Dan Houder, President and Publisher.

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 800-531-1026.