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Inside this issue

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Quest Settlement Could Reignite Debate Over Discounted Lab Pricing

Quest Diagnostics' recently announced $241 million settlement with the state of California over allegations that it overcharged the state's Medicaid program (Medi-Cal) for covered clinical laboratory tests could reignite the debate over discounted lab pricing.

At a time when the federal government and states are facing record budget deficits, the implication of the California case and associated settlements could well be profound if and when lowest pricing spreads to other states and even nationwide as federal policymakers look to find more Medicare savings. Already several states, including Florida, Massachusetts, Michigan, New York, and Virginia, have indicated that they are scrutinizing lab billings.

The issue of lowest lab pricing is nothing new. Under the Social Security Act, Medicare providers (including labs and pathologists) may not charge Medicare an amount "substantially in excess" of the suppliers' "usual charges." The Department of Health and Human Services has tried, unsuccessfully, several times to define "substantially in excess"

Continued on page 9

Draft FDA Guidance Would Restrict RUO and IUO Reagent Instruments

The Food and Drug Administration (FDA) has issued draft guidance that would limit the sale and distribution of "Research Use Only" (RUO) and "Investigational Use Only" (IUO) products. While most of the restrictions set out in the policy are consistent with the current practices of many companies, in several key areas the agency's proposals would substantially curb the sale of RUO- and IUO-labeled products, according to the law firm of Hyman, Phelps and McNamara (Washington, D.C.).

"Most significantly, FDA has departed from the well-established practice of determining intended use based on the manufacturer's conduct, rather than how a customer uses the product," write attorneys Jamie Wolszon and Jeffrey Gibbs on the firm's FDA law blog (*www.fdalawblog.net*). "FDA states in the draft guidance that a manufacturer must stop sales of its RUO or IUO product to a customer once the manufacturer knows—"or has reason to know"—that the customer is using the product for a diagnostic use, even if the manufacturer makes no diagnostic claims or statements."

Continued on page 2

Draft FDA Guidance, *from page 1*

According to the FDA, the marketing of unapproved and uncleared IVD products for purposes other than research or investigation (for clinical diagnostic use, for example) has led in some cases to diagnostic use of laboratory tests with unproven performance characteristics and manufacturing controls that are inadequate to ensure consistent manufacturing of the finished product.

> ***"It is not clear what FDA's basis is in confining the category of research products to ones used to advance 'novel and fundamental' objectives, It is clear that this limitation will be both difficult to apply and controversial."***
>
> ***– FDA Law Blog***

Use of such tests for clinical diagnostic purposes may mislead health care providers and cause serious adverse health consequences to patients who are not aware that they are being diagnosed with research or investigational products, says FDA in the draft guidance.

The guidance addresses labeling requirements regarding IVD products, as well as the types of products the FDA generally considers to be RUO or IUO products. Several of the basic requirements to qualify as an RUO or an IUO have not changed.

However, in one departure from current thinking, FDA says that products "intended for use in nonclinical laboratory research with goals unrelated to development of a commercial product, such as discovering and developing novel and fundamental medical knowledge related to human disease and conditions" could qualify as RUO. The agency provides as examples "instruments and reagents intended for use in research attempting to isolate a gene linked with particular disease when such instruments and reagents are not intended to produce results for clinical use."

According to Wolzson and Gibbs, this is a narrower interpretation of "research" than is commonly understood. "It is not clear what FDA's basis is in confining the category of research products to ones used to advance 'novel and fundamental' objectives," they write. "It is clear that this limitation will be both difficult to apply and controversial."

Intended Use vs. Actual Use

FDA states that in determining whether a product is properly marketed as RUO or IUO, it will consider the manufacturer's statements and claims about its products. However, the agency also said it would consider the manufacturer's knowledge of the customer's intended use.

FDA says it is aware that laboratories sometimes use IVD products labeled RUO in clinical diagnosis and that many manufacturers, importers, and distributors of IVD products labeled RUO are also aware of such use.

"Manufacturers who label their IVD products: 'For Research Use Only. Not for use in diagnostic procedures,' should not sell such products to laboratories that they know use the product for clinical diagnostic use," says the FDA. "If a manufacturer learns that a laboratory to which it sells its RUO-labeled IVD product is using it in clinical diagnosis, it should halt such sales or comply with FDA requirements for IVD products, including premarket review requirements, if applicable.

"FDA fully supports the use of IVD products labeled RUO for research purposes, but since these products may not be manufactured in accordance with [Current]

Good Manufacturing Practices (cGMP) and their performance characteristics have not been established, we believe they present a serious potential risk to the public health when used in clinical laboratories to generate tests results intended for patient management."

The same policy applies to manufacturers who label their IVD products IUO, says the FDA. If a manufacturer learns that a clinical laboratory to which it sells its IUO-labeled IVD product is using them for noninvestigational diagnostic use, it should halt sales for such use or comply with FDA regulations for such products.

"This position that a company should discontinue sales to a customer because that customer is using the product in a manner outside the labeling may be unprecedented," write Wolszon and Gibbs. "Significantly, the draft guidance includes no provision for manufacturers first to inform the customer that it must stop diagnostic use or take other measures to alter the manner of usage. Rather, the FDA is apparently saying that the manufacturer has no option but to cease sales immediately."

Comments on the draft guidance are due by Aug. 30, 2011. The guidance is available online at *www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm253307.htm.* G2

FDA Issues Draft Guidance for In Vitro Devices To Screen for Chlamydia, Gonorrhea

The Food and Drug Administration May 11 issued a draft guidance to provide industry and agency staff with recommendations for studies to establish the analytical and clinical performance of in vitro diagnostic devices (IVDs) intended to screen and diagnose Chlamydia trachomatis and/or Neisseria gonorrhoeae using nucleic acid-based assays.

A manufacturer who intends to market an IVD device for C. trachomatis and/or N. gonorrhoeae screening and diagnostic testing must conform to the general controls of the Federal Food, Drug, and Cosmetic Act and get premarket clearance or approval before marketing the device.

The guidance, *Establishing the Performance Characteristics of In Vitro Diagnostic Devices for Chlamydia trachomatis and/or Neisseria gonorrhoea: Screening and Diagnostic Testing*, is not final, nor is it in effect, FDA said in a *Federal Register* notice. Comments are due on the draft guidance by Aug. 9, 2011, FDA said.

The guidance provides detailed information on the types of studies FDA recommends to support class I and class II premarket submissions (510(k) premarket clearances or de novo classification petitions) for devices that detect one specific organism, as well as devices that may detect both organisms with or without further differentiation, the agency said.

A manufacturer who intends to market an IVD device for C. trachomatis and/or N. gonorrhoeae screening and diagnostic testing must conform to the general controls of the Federal Food, Drug, and Cosmetic Act and get premarket clearance or approval before marketing the device.

Chlamydia trachomatis is the most prevalent bacterial sexually transmitted infection in the United States. Because the majority of C. trachomatis infections are subclinical, the Centers for Disease Control and Prevention (CDC) has recommended annual screening of all sexually active women under the age of 26, FDA said in the guidance.

"Failure of devices for detection of C. trachomatis to perform as expected or failure to correctly interpret results may lead to incorrect patient management decisions and inappropriate public health responses. In the context of individual patient management, a false negative report could lead to delays in providing (or failure to provide) definitive diagnosis and appropriate treatment and infection control and prevention measures," FDA said.

The agency noted that "a false positive report could lead to unnecessary or inappropriate treatment or unnecessary control and prevention actions. Therefore, establishing the performance of these devices and understanding the risks that might be associated with the use of these devices is critical to their safe and effective use."

Gonorrhea was the second-most commonly reported notifiable disease in the United States as of 2008, the FDA document said. According to the document, CDC estimates that more than 700,000 people in the United States get new gonorrheal infections each year. It is estimated that only about half of these infections are reported to CDC, FDA said.

The guidance is available online at *www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm254813.htm.*

FDA Issues New Warnings on Direct-to-Consumer Genetic Tests

Tougher oversight of direct-to-consumer testing is expected to be part of the FDA guidance, currently under review, on new regulation of laboratory-developed tests (LDTs), agency officials have stated at numerous public forums in recent months.

In the latest crackdown on genetic test kits marketed to consumers, the Food and Drug Administration has sent warning letters to three companies stating that their products "appear to be medical devices" requiring premarket approval by the agency.

The companies and test kits cited are:

- Precision Quality DNA (Fallon, Nev.): Precision Quality DNA, targeting genes such as BRCA1 and BRCA2 to determine risk factors or likely response to a particular drug.
- Lumigenix Inc. (Palo Alto, Calif.): Comprehensive Kit, for genetic predisposition for 79 disease conditions such as breast cancer and intended to help individuals take steps to maximize their health.
- American International Biotechnology Services (Richmond, Va.): Sports X Factor Test Kit, also referred to as Sports X Factor Genetic Athletic Assessment Test, aimed at athletes and parents of young sports competitors to provide information about potential health conditions, including undiagnosed heart conditions.

In the May 11 letter, the FDA requested a response within 15 days as to why the companies believe their services can be legally marketed without premarket clearance.

Tougher oversight of direct-to-consumer testing is expected to be part of the FDA guidance, currently under review, on new regulation of laboratory-developed tests (LDTs), agency officials have stated at numerous public forums in recent months.

The FDA announced in July 2010 that it planned to expand its regulatory reach to include LDTs based on their level of risk and solicited comments from stakeholders. LDTs are in vitro diagnostics manufactured by and offered in the same CLIA-certified laboratory. Currently, the FDA has limited its enforcement discretion to analyte-specific reagents and in vitro diagnostic multivariate index assays (IVDMIAs) using a proprietary algorithm to produce patient-specific results.

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COMPLIANCE PERSPECTIVES

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A New Approach to Surveys: Building Quality From the Inside

Building a culture of quality in laboratories is not something that can be assigned to one individual or department, nor outsourced to consultants or accrediting agencies. Quality is a management responsibility. Practically speaking, it requires systems and tools to transform the organization from a reactive to a proactive mode of operation—tools to identify, quantitate, and systematically reduce errors. Most importantly, it requires leadership, tenacity, and discipline to ensure that quality is not one of the things we do, but the way we do everything.

The laboratory industry is only beginning to scratch the surface of quality. It is a long way from achieving the levels of quality that other industries such as manufacturing achieved decades ago. According to James Westgard,[1] laboratory testing today operates in the three sigma range or 66,800 defects per million opportunities. This is embarrassingly poor performance and is comparable to the quality level achieved in baggage handling by major airlines. It is ironic that in health care we cannot even come close to achieving the same level of quality that we demand in a television or an automobile!

Until recently, the knowledge that health care—like all industries—has errors was reserved for insiders. Errors were not openly reported or discussed because we did not want the public to know how error-prone health care truly is. Information on quality metrics is now readily available to the public and will increasingly drive reimbursement and market share. As leaders in our industry and organizations, we have a responsibility to restore quality and confidence.

The government attempts to ensure quality in health care through the licensing, inspection, and accreditation process. However, the attributes of laboratories with regulatory problems examined in this article will demonstrate that this approach is fundamentally flawed. Consider the following:

1 The analytical processes of laboratories today operate at three to four sigma compared to the "world-class quality" of six sigma achieved in manufacturing.

2 The U.S. Government Accountability Office (GAO) released a scathing report on quality in the laboratory industry indicating that quality in hospital laboratories as measured by failures in proficiency testing had not improved in the prior five years.[2]

3 A survey by Chi Solutions and G2 Intelligence[3] found that:

- Less than 20 percent of laboratories understand that the laboratory director has ultimate responsibility for quality;

[1] *Westgard, J.O. Back to the Future of Laboratory Quality. Presented at G2 Intelligence and Chi Solutions Inc., Lab Quality Symposium; Sept. 27, 2006, Washington, D.C.*

[2] *United States Government Accountability Office (GAO): Report on* Clinical Lab Quality: CMS and Survey Organization Oversight Should Be Strengthened, *June 2006.*

[3] *Murphy, K.A. Quality Survey 2006. Presented at G2 Intelligence and Chi Solutions Inc., Lab Quality Symposium, Sept. 27, 2006, Washington, D.C.*

- Only 50 percent to 60 percent of respondents benchmark quality against peers;
- In only about half is there some form of electronic reporting system for errors;
- Less than half of respondents measure test result turnaround time (TAT) the way their physician customers do (from order to result); and
- Sixty-five percent do not know the number of sentinel events in their organizations.

These findings are sobering and indicate that what we are doing now—inspecting quality from the outside—is clearly not working. It is time for a different approach, time to build quality from the inside. This article will explore the common themes of laboratories with quality and regulatory problems and identify frequently cited deficiencies. A second article, to be published in the September issue of *G2 Compliance Report*, will propose practical tips and solutions for remediation.

Most Common Deficiencies

During a survey by the Centers for Medicare and Medicaid Services (CMS), the inspector assesses the laboratory operation and, depending on the severity of the deficiencies, may document noncompliance at two different levels: conditional and standard. If an accredited laboratory is out of compliance with one or more condition-level requirements, it is subject to a variety of potential sanctions, the most severe being revocation of the CLIA certificate and suspension of all Medicare payments. The severity of the noncompliance and the potential for harm to patients are factors in determining the corrective actions required by the laboratory and the ultimate sanctions imposed by CMS.

CMS's Top 10 Condition-Level Deficiencies

#	CITATION	% LABS CITED
1	Moderate Complexity Laboratory Director Qualifications/ Responsibilities	4.4
2	Successful Proficiency Testing Participation	4.1
3	Proficiency Testing Enrollment	1.9
4	Analytic Systems (Quality Control)	1.9
5	Moderate Complexity Testing Personnel	1.5
6	High Complexity Director Qualifications/Responsibilities	1.2
7	Technical Consultant Qualifications/Responsibilities	0.9
8	Hematology	0.6
9	Bacteriology	0.4
10	General Laboratory Systems	0.3

Source: Yost, J., CLIA Compliance 2010: What's Next from CMS? G2 Intelligence, webinar; March 16, 2010 (Data from CMS CLIA Database, October 2009).

In a March 2010 G2 Intelligence webinar,[4] Judy Yost, director of the division of laboratory services at CMS, shared lists of the 10 most commonly cited condition-level and standard-level deficiencies. The laboratory is given a period in which to respond to the deficiencies as well as an explanation of the sanctions to be imposed if the situation is not corrected. The facility must respond in writing to each of the deficiencies with a plan of correction that is acceptable to CMS. While a standard response format is not required, the following components must be included in the plan of correction:[5]

- What corrective actions are to be taken to correct each deficiency;
- When the actions will be completed;
- Who is responsible for implementing the stated corrective actions;
- Who is responsible for ensuring the corrective actions resolve the deficiency;
- How corrective actions will be monitored; and
- Evidence of laboratory director review of the completed plan of correction (document must be signed and dated before it is submitted to CMS).

[4] *Yost, J. CLIA Compliance 2010: What's Next from CMS? G2 Intelligence Webinar, March 16, 2010.*
[5] *Laessing, R.H., Ehrmeyer S.S. New Poor Man's (Person's) Guide to Meeting the Regulations. Madison, Wis.; R&S Consultants, November 2008.*

Since follow-up inspections are often planned to ensure that corrective actions have been effective, it is essential that a laboratory carry out the actions it has stated it will complete. If the laboratory is unable to accomplish the corrective actions within the required response period, an implementation timeline should be provided with follow-up documentation presented to CMS upon completion.

Laboratories in Trouble: Common Themes

From 2004 to 2006, a scandal at Maryland General Hospital (MGH) and other laboratories in the Baltimore area resulted in scathing press and Senate hearings about the failures of the regulatory process. Many comforted themselves by thinking that this could never happen to them. Recent experience, however, points to the contrary, as health care organizations throughout the country continue to find themselves faced with similar regulatory challenges. Some of the facilities involved have had even more adverse outcomes than MGH.

CMS's Top 10 Standard-Level Deficiencies

#	CITATION	% LABS CITED
1	Policy for Proper Reagent Storage	6.9
2	Verify Accuracy of Non-Proficiency Tested Tests	6.3
3	Analytic Systems' Quality Assessment	5.7
4	Follow Manufacturer's Instructions	5.1
5	Procedure Manual	4.7
6	Laboratory Director Responsibility—Quality Assessment Plan	4.6
7	Calibration Verification	4.4
8	Moderate Complexity Laboratory Director Qualifications/ Responsibilities	4.4
9	Use of Expired Reagents	4.2
10	General Laboratory Systems Quality Assessment	4.1

Source: Yost, J. CLIA Compliance 2010: What's Next from CMS? G2 Intelligence, webinar; March 16, 2010 (Data from CMS CLIA Database, October 2009).

Seven themes that have been commonly observed in laboratories with regulatory difficulties are as follows:

1 Weak Management at All Levels: The first common theme is weak management, within both the laboratory and the organization as a whole. Facilities with regulatory problems generally have laboratory directors who are overwhelmed or uninvolved. The CLIA-defined laboratory director responsibilities usually fall to a pathologist or medical practice physician who has no specific training or experience in laboratory management. Also, financial incentives are misaligned. With most of a pathologist's compensation coming from anatomic pathology, there is little incentive to become actively involved in clinical pathology. Organizations with laboratories in trouble are often found to have weak management overall—human resources and administration were aware of the problems but failed to heed the warning signs. This was certainly true at Maryland General. The fallout of poor management was substantial; the laboratory director resigned and the laboratory administrator, vice president of operations, and CEO all lost their jobs. They learned the hard way that not paying attention to quality can be a career-limiting event.

2 Limited Regulatory Knowledge: Most laboratories have one designated individual to oversee quality. The laboratory director delegates responsibility for overseeing quality functions to a quality manager, and this individual updates the laboratory regarding changes to regulations and ensures ongoing compliance. Laboratories get into trouble when all regulatory knowledge lies with one person or there is no process to ensure that new regulatory requirements are incorporated into daily laboratory practice. During this past year, a new trend has emerged as a direct result of the shortage of medical technologists and the scarcity of technologists who want to pursue and have an aptitude for management. Nontechnical

managers are being hired for jobs that were once the domain of technical managers. These individuals lack the technical expertise to judge whether adequate quality systems are in place or practice.

3 Incomplete Documentation: If deficiencies are found during an inspection, most laboratories can develop an acceptable initial plan of correction. The challenge lies with sustained follow-up. The new practices may not be maintained, resulting in repeat deficiencies. Second, document control can be problematic. There may be a lack of adequate documentation or a discrepancy between documentation and actual practice. Organizations must remember to document what they do and do what they have documented!

4 Cost-Driven to the Extreme: Shrinking reimbursement in health care forces hospitals to be cost-conscious. However, some take this to the extreme, to the point where cost is all-important. A laboratory can look like a star from an economic point of view but actually be in danger of compromised quality of testing. Examples exist of laboratories that appear to be "best or top performers" by benchmarking standards for cost but which are understaffed by 20 percent or more, have turnover rates in excess of 30 percent, and force nontechnical staff to do technical jobs. These facilities have quality problems, but judged by economic standards alone, they appear to be top performers with low labor costs and high technical productivity. Organizations that are solely numbers-driven may appear successful but will ultimately be driven down by poor quality.

5 Unhealthy Culture: Another theme in common is an "unhealthy" culture. The organization is veiled in incompetence and secrecy, and no one wants to hear about problems. Sometimes it goes beyond lack of recognition or action to punitive measures against those who speak up. As a result, accrediting agencies have established toll-free hot lines for reporting quality problems and protections for whistleblowers.

6 Reliance on Outsiders for Quality: Many managers today rely on inspections to monitor quality and mistakenly equate the absence of numerous deficiencies in an inspection with good quality. This is not true. There have been cases in which multiple accrediting agencies failed to find the problems in troubled laboratories. In the past, these same agencies have been criticized for lack of consistency within and across organizations, inconsistent training for inspectors, and failures of inspection methodologies. Changes have occurred in the industry in the wake of the laboratory scandals, but most facilities that have experienced an unannounced inspection report little difference compared to prior inspections. It is important to ask what, if anything, has really changed and if inspections adequately detect poor quality.

7 Reactive Organizations: Most laboratories today approach quality reactively rather than proactively. Quality is a plan on the shelf. Instead, they "get ready" for inspections. They rely on outside agencies to identify their problems and collect some quality data but do not really do anything with it. The health care industry is partly to blame because it tolerates poor quality. Organizations often lack an understanding of true quality systems and do not have the necessary tools to detect problems and trends and systematically improve performance. In addition, quality is relegated to middle management or just one individual rather than being driven at the top. Most middle managers in health care today are overwhelmed and trying to survive day to day.

The September Perspectives article will examine key strategies for ensuring quality in clinical laboratories.

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Quest Settlement Could Reignite Debate, *from page 1*

and "usual charges." The most recent attempt, a 2003 proposed rule, was withdrawn in 2007. The California case and Quest settlement, however, could lead the federal government and the states to take another look at the issue.

"There is speculation that this could go beyond California, especially in this day and age when state Medicaid programs are looking for money," says Patric Hooper, Esq., a partner with the law firm Hooper Lundy Bookman. "This issue had been around for 30 years, but it seems to have new life now."

Quest Denies Allegations

Quest said May 19 that it had finalized an agreement to settle a lawsuit brought by a competitor for $241 million. The lawsuit, in which the state of California intervened, alleged that Quest and five other clinical laboratories, including LabCorp, did not comply with California's "comparable charge" regulations, resulting in overpayment by Medi-Cal.

Patric Hooper and David Nichols, president and founder of Nichols Management Group, will discuss the issue of lowest lab pricing at this year's Lab Institute, which will be held Oct. 19-21 in Arlington, Va. For details, or to register, go to www.labinstitute.com.

In addition to the $241 million settlement, Quest also agreed to price-reporting obligations for a limited time and, in lieu of such obligations for a transition period, to provide Medi-Cal with a discount until the end of July 2012. In reaching the settlement, the company admitted no wrongdoing but sought to avoid the risk, time, and expense of a lengthy litigation.

"Our laboratory testing services for Medi-Cal were priced appropriately, and we deny all allegations in the complaint," said Michael Prevoznik, senior vice president and general counsel of Quest Diagnostics, in a statement. "Quest Diagnostics operates with the highest standards of integrity and fairness. California's interpretation of the Medi-Cal 'comparable charge' regulations created uncertainty and resulted in an intolerable business environment for us. This agreement allows us to put the lawsuit behind us and provides for an orderly process for resolving any remaining interpretation issues. We also intend to pursue other avenues, including legislative action, to ensure clear regulatory standards in California for the clinical laboratory industry."

The settlement with Quest is the largest recovery under the state's False Claims Act, said the attorney general's office. Hunter Laboratories CEO Chris Riedel, who filed the qui tam lawsuit, stands to gain 15 percent to 25 percent of the recovery.

Meanwhile, LabCorp reported that California is seeking $97.5 million for its alleged overcharges, including interest, from November 1995 through November 2009. The company is currently scheduled to go to trial in January 2012 but reportedly is trying to reach a settlement. Others named in the lawsuit have either settled or been dropped from settlement discussions.

CMS Launches Pioneer ACO Program, Other Initiatives to Encourage Participation

The Centers for Medicare and Medicaid Services May 17 announced three initiatives under the Patient Protection and Affordable Care Act's Center for Medicare and Medicaid Innovation designed to encourage providers to form accountable care organizations (ACOs).

First, the CMMI will support the Pioneer ACO model, which is designed to provide an accelerated pathway for advanced organizations ready to participate in shared savings. Under this model, Medicare could save up to $430 million over three years by better coordinating patient care, CMS said.

The Pioneer model will allow the advanced 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 Medicare Shared Savings Program.

In the May 20 *Federal Register,* CMS requested applications for organizations to participate in the Pioneer ACO model from the third or fourth quarter of 2011 to December 2016. Organizations must submit a nonbinding letter of intent by June 10, the agency said in the notice.

In a May 17 call with reporters, CMS Administrator Donald Berwick said the Pioneer model will allow the advanced 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 Medicare Shared Savings Program. Berwick said the model is designed to work in coordination with private payers by aligning provider incentives, which will improve quality and health outcomes for patients across the ACO and achieve cost savings for Medicare, employers, and patients.

ACOs are voluntary groups of doctors and hospitals organized to improve coordination of care for Medicare beneficiaries. Under the Medicare Shared Savings Program, which will begin Jan. 1, 2012, ACOs will be eligible to receive shared savings if they demonstrate they have reduced costs and improved their patients' quality of care. CMS's proposed rule on ACOs was published in the April 7 *Federal Register.*

Pioneer Model: Higher Savings and Risk

ACOs may participate in either the shared savings program or in the Pioneer model, but not in both concurrently, CMS said. Pioneer model agreements will consist of three performance periods. The first will last from the start date of the initiative (anticipated to be the third or fourth quarter of 2011) until Dec. 31, 2012. Subsequent performance periods will each last 12 months, CMS said.

The payment models being tested in the first two years of the Pioneer model are a shared savings payment policy with generally higher levels of shared savings and risk for Pioneer ACOs than levels proposed in the Medicare Shared Savings Program. In year three of the program, CMS said participating ACOs that have shown a specified level of savings over the first two years will be eligible to move a substantial portion of their payments to a population-based model. These models of payments will also be flexible to accommodate the specific organizational and market conditions in which Pioneer ACOs work.

CMMI acting Director Richard Gilfillan said during the call that CMS expects about 30 organizations to test the Pioneer model and that it should take effect this fall. CMS will publicly report the performance of Pioneer ACOs on quality metrics, including patient experience ratings, on its Web site.

Beneficiary Alignment

Gilfillan said that Medicare beneficiaries will remain free to select the providers and services of their choice if they are enrolled in a Pioneer ACO. The model does not include restrictions on or changes to Medicare fee-for-service benefits, nor does it include provisions for beneficiaries to opt out of alignment with a Pioneer ACO for purposes of expenditure calculations and quality performance measurement.

Any future possible provisions for beneficiaries to opt out of expenditure calculations and quality measurement will mirror those in the final regulations for the Medicare Shared Savings Program, CMS said.

The Pioneer model may include either prospective or retrospective alignment of beneficiaries. Pioneer ACOs that select prospective alignment will be accountable for the cost and quality outcomes of all their prospectively aligned beneficiaries at each end-of-period reconciliation, with certain exceptions, CMS said. Under prospective alignment, CMS will identify the population of Medicare beneficiaries for whom an ACO is accountable through analysis of the prior three years of fee-for-service claims data, according to the agency.

Under the shared savings program, beneficiaries are aligned with an ACO retrospectively. CMS said it "will use the retrospective alignment processes of the Shared Savings Program with changes as necessary to reflect differences in related design criteria between the two models."

Advance Payment Initiative

In addition to the Pioneer model, CMS also announced May 17 that it is seeking input on the idea of an Advance Payment ACO model.

CMS said the innovation center is considering an Advance Payment Initiative for ACOs entering the Medicare Shared Savings Program to test whether and how prepaying a portion of future shared savings could increase participation.

CMS said the innovation center is considering an Advance Payment Initiative for ACOs entering the Medicare Shared Savings Program to test whether and how prepaying a portion of future shared savings could increase participation.

According to the agency, "some providers have expressed a concern about their lack of ready access to the capital needed to invest in infrastructure and staff for care coordination. Under the proposed initiative, eligible organizations could receive an advance on the shared savings they are expected to earn as a monthly payment for each aligned Medicare beneficiary. ACOs would need to provide a plan for using these funds to build care coordination capabilities, and meet other organizational criteria. Advance payments would be recouped through the ACOs' earned shared savings." Comments should be submitted by June 17, CMS said.

Providers Approve

CMS's announcement was embraced by provider groups, who have recently been critical of the proposed ACO rule.

Blair Childs, senior vice president of public affairs at the Premier health care alliance, commended CMS for recognizing that "ACOs are at different points in their journey to deliver accountable care, with some prepared to launch quickly, while others require more time, resources, and knowledge before they commit. As ACOs are local and subject to regional market conditions, CMS's decision to create multiple and accelerated tracks will allow a variety of approaches to be tested."

The American Medical Association said in a statement the ACO initiatives "take a step in the right direction, but more action is needed to ensure all physicians who wish to do so can lead and participate in Medicare ACOs. The AMA is pleased that [the innovation center] is working to assist physicians at varying stages of readiness who want to participate in Medicare ACOs. The benefits of this new care delivery model cannot be fully realized unless physicians in all practice sizes can be involved."

News-At-A-Glance

PATHOLOGISTS UNABLE TO MEET MEANINGFUL USE: Pathologists cannot meet the majority of current objectives in the federal meaningful use program to qualify for an incentive as they are outside the scope of the specialty's practice, according to the College of American Pathologists (CAP). As a result, they would be at risk for penalties under Medicare starting in 2015. David Booker, M.D., a member of the CAP board of governors, testified during a federal health information technology meeting May 13 that pathologists generally do not use—nor have access to—electronic health records (EHRs). Rather, they have long relied on laboratory information systems (LISs) to support the work of analyzing patient specimens and generating test results. Providers who can demonstrate "meaningful use" through EHRs are eligible for incentive payments beginning in 2011. Physicians who do not adopt an EHR by 2015 will be penalized 1 percent of Medicare payments, increasing to 3 percent over three years.

OIG APPROVES PATIENT ASSISTANCE PROGRAM: A nonprofit group's program to help needy individuals pay cost sharing for drugs and genetic testing may expand to provide assistance with insurance premiums without being subject to civil monetary penalties, according to a modified advisory opinion (No. 10-07) from the Department of Health and Human Services Office of Inspector General, posted May 26. The original advisory opinion addressed the organization's program to help needy individuals pay for the diagnosis of three specific diseases—multiple sclerosis, cancer, and rheumatoid arthritis—and for the drugs to treat those conditions. In the request for modification, the organization asked for and was granted the flexibility to assist people with diseases not mentioned in the original advisory opinion and to aid them in paying their insurance premiums. The assistance with insurance premiums would be subject to the same or equivalent safeguards already approved in the original advisory opinion. The OIG said that while the modifications could possibly result in prohibited remuneration under the anti-kickback statute, it would not impose administrative sanctions on the requestor under the anti-kickback statute.

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