G2 Compliance Report

INTELLIGENCE

For Hospitals, Laboratories and Physician Practices

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LDT Guidance Likely to Contain Exceptions

The Food and Drug Administration's (FDA) long-awaited guidance on lab-developed tests—which is currently under review—is likely to contain exceptions for certain types of tests, such as those for rare diseases, biothreats, and emerging infectious diseases, as well as for "traditional, low-risk" tests, according to Alberto Guiterrez, Ph.D., director of FDA's Office of In Vitro Diagnostic Device Evaluation and Safety.

While Guiterrez, who spoke at the annual meeting of the American Clinical Laboratory Association (ACLA) April 20, would not say when the LDT guidance would be released since the review is taking longer than he expected, he seemed hopeful that it could be issued within the next six months. The guidance is expected to set up a regulatory framework for LDTs based on risk and is likely to contain requirements for registration of LDTs and a mechanism for classifying them, explained Guiterrez.

Those tests classified as Class III medical devices, such as those for human papillomavirus (HPV), would probably be required to go through the FDA's 510(k) approval process, while those classified as Class I devices probably would not, he said.

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FTC Dismisses Challenge to Merger of LabCorp and Westcliff

The Federal Trade Commission (FTC) announced April 22 that it dismissed an administrative enforcement action challenging Laboratory Corporation of America's $57.5 million acquisition of Westcliff Medical Laboratories.

The FTC, on a 5-0 vote, said it was abandoning its administrative enforcement action after it was unable to obtain an injunction from a federal trial court to prevent consummation of the merger while the administrative action proceeded. FTC Chairman Jon Leibowitz and Commissioners William Kovacic and Edith Ramirez said in a statement that further adjudication of the matter would "not serve the public interest." Commissioner Julie Brill, in a separate concurrence, "reluctantly" concluded that "the costs of continuing with administrative litigation outweigh the potential benefits of doing so."

The action follows the commission's March 23 decision to withdraw its appeal of the trial court's Feb. 22 order that left LabCorp free to proceed with its integration of the Westcliff assets. The U.S. Court of

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LTD Guidance, *from page 1*

Guiterrez also indicated that the agency's guidance on companion diagnostics should be out soon and that clinical trial guidance for both therapeutics and diagnostics should be released by July 31.

While the FDA is working on a regulatory framework for LDTs, ACLA is planning to pursue an alternate strategy for regulation of such tests, according to Alan Mertz, president. ACLA would prefer to see LDTs regulated under the Clinical Laboratory Improvement Amendments (CLIA) and is planning to seek a statutory change that would specify such oversight, Mertz told G2 Intelligence.

CMS Drops Proposed Cytology Proficiency Testing Rule

The Centers for Medicare and Medicaid Services (CMS) is withdrawing its proposed rulemaking to revise requirements for gynecologic cytology proficiency testing under the Clinical Laboratory Improvement Amendments (CLIA).

In an April 8 memo to state survey agency directors, CMS said there was a lack of consensus and support for the changes envisioned in the rulemaking. CLIA officials had said during the September 2010 meeting of the Clinical Laboratory Improvement Advisory Committee (CLIAC) that the agency was considering this move.

In making the withdrawal official, Thomas E. Hamilton, director of the CMS survey and certification group, said in the memo, "CMS was acting in response to comments it received on the proposed revisions, the greater percentage of which requested replacement of the current proficiency testing (PT) program with a continuing education program."

This conflicts with CMS's interpretation that the CLIA statutory language requires the testing of individuals, he said. Critics contend this is too narrow a reading of the law and that testing the lab as a whole, as is the case with noncytology PT, is a better way to ensure Pap smear quality results.

Despite withdrawal of the proposal, Hamilton noted, the CLIA program will implement the majority of CLIAC-endorsed PT recommendations "where the comments from the public and the cytology community demonstrate consensus and CMS sees benefit."

Changes to Be Made

Using surveyor interpretive guidance and administrative policy, CMS will implement the following:

- Encourage labs to participate in educational lab programs in addition to individual PT;
- Change the current term of "slides" to "challenges";
- Define a challenge as case equivalent;
- Retain four response categories and continue to require at least one challenge from each of the four categories in each test;
- Require field validation, monitor challenges continuously, and remove challenges that fail field validation;
- Require vendors to disclose field validation procedures;
- Provide educational feedback for result discrepancies;
- Continue to allow PT providers to determine proctor requirements;

- Require PT providers to disclose their appeals process in writing; and
- Change language to state "individuals who score <90" as opposed to using the word "fail."

Changes Not to Be Made

What will not be implemented at this time, Hamilton said, are the following:

- Reduce the frequency of testing to a three-year cycle;
- Use 20 challenges for every test (initial test and retest);
- Change the grading scheme to a new model that is the same for both technical supervisors and cytotechnologists;
- Require biopsy confirmation of category D (HSIL/cancer) challenges but not category C (LSIL) challenges;
- Add a transition phase for new technology such as virtual slides when the individual can request retesting with the previous platform or format (e.g., glass slides); and
- Require oversight organizations and agencies to determine if labs participate in educational programs and provide labs with identification of available resources.

PT Proposal Controversial From the Start

The cytology PT rulemaking, issued Jan. 16, 2009, called for lengthening the testing interval, increasing the minimum number of slides (challenges) per testing event, requiring validation of cytology challenges before use in testing, and allowing for new technologies, for example, digital images, as they become available.

CMS estimated it would impact 2,142 cytology laboratories and 12,831 individuals who screen or interpret 65 million gynecologic cytology preparations in the United States each year.

The cytology PT rulemaking, issued Jan. 16, 2009, called for lengthening the testing interval, increasing the minimum number of slides (challenges) per testing event, requiring validation of cytology challenges before use in testing, and allowing for new technologies, for example, digital images, as they become available.

The proposals were based on recommendations of a work group convened by CLIAC and later endorsed by the full committee. But the rulemaking triggered opposition from the cytology community at the outset when CMS insisted that the CLIA statute requires PT of individuals and any change in this regard was off limits.

In refusing to budge, Hamilton's memo faulted cytology continuing education programs for not meeting the law's requirements for the number and frequency of slides to be tested. "Additionally, the evaluation of results performed by [these] programs is not sufficient to satisfy the statute and regulations, as participation in continuing education is voluntary, and the programs have no oversight authority. The educational challenges provided by continuing education programs are initially performed independently by each individual who reads and interprets cytology slides, but a consensus answer is provided to the educational program on behalf of the entire lab. Credits earned for participation are granted to participants even when there is a failure to successfully identify the challenge, which may disguise poor performers.

"Replacing the current requirements with continuing education would introduce risk to the CLIA program. The current system already includes continuing education tailored to individual areas of failure, and the proposed change would diminish CMS' ability to oversee, monitor, and enforce quality testing through cytology PT which has demonstrated proven success."

In calling for an alternative PT approach, the broad-based 60-member cytology PT coalition has argued that the current regulations, initially written in 1992, have not kept pace with the latest science and technology. The coalition asserts that the statutory language can accommodate alternative education-based programs to assess proficiency. In the 110th Congress the coalition gathered bipartisan support behind legislation for this purpose. The measure passed the House and got 43 co-sponsors in the Senate but no further action was taken before the session closed in January 2009.

In calling for an alternative PT approach, the broad-based 60-member cytology PT coalition has argued that the current regulations, initially written in 1992, have not kept pace with the latest science and technology.

CMS resolutely defends the current cytology PT program, citing success in improving quality and reducing errors, based on PT results since nationwide testing began in 2005. According to the April 8 memo, "The number of individuals who scored less than the passing score of 90 percent has decreased significantly over time." Improvements in participant scores may be due to post-failure continuing education and greater comfort with the testing process, the memo concluded.

There are two CMS-approved national PT providers: the College of American Pathologists and the American Society for Clinical Pathology. The state of Maryland runs an approved program for testing individuals who examine Pap smears from Maryland residents.

Lab Copay Proposal Could Be Resurrected

Though the clinical laboratory industry has fought off several attempts in recent years to implement a lab copay on Medicare beneficiaries, this highly unpopular—and controversial—proposal could rear its head once again.

Speaking at the annual meeting of the American Clinical Laboratory Association (ACLA) April 19, Chuck Clapton, health policy director for the Senate Health, Education, Labor, and Pensions (HELP) Committee, predicted that the copay could once again become part of congressional discussions to offset Medicare costs.

The copay issue has been bandied about at least twice in recent years, the last time in 2009 when the Senate Finance Committee proposed it as one legislative option to help finance health reform legislation. The committee proposed a uniform 20 percent coinsurance for all Medicare Part B services, including preventive and diagnostic clinical laboratory services. The lab industry lobbied vigorously against such copays, arguing that they would shift an entirely new cost burden to Medicare beneficiaries. The AARP also explicitly rejected copays. Ultimately, the Senate Finance Committee withdrew the copay proposal.

While many in the industry hoped the copay issue was laid to rest, Clapton explained that given the current federal budget deficit, all potential sources of revenue must be considered. G2 Intelligence will keep a close eye on developments during the budget negotiations and will keep you informed about any proposals that could affect beneficiary access to laboratory testing services.

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COMPLIANCE PERSPECTIVES

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Health Care Market Reforms: Implications and Prescriptions for Laboratories

Reforming the U.S. health care system is inevitable. The increasing cost of care is unsustainable and concerns abound about systematic inefficiencies and the quality of care delivered. Policymakers have converged on a basic set of key principles that underlie many of the initiatives being pursued:

- *Payment reform*—shifting the current fee-for-service (FFS) payment system to paying for value of services provided, not quantity of services;
- *Value and accountability reform*—making providers accountable for costs and value through payment allocation across populations, episodes of care, or bundles of provider services;
- *Care coordination reform*—having providers coordinate their services so that services are more efficient, more patient-centered, and higher quality;
- *Patient-centered care reform*—engaging patients and designating a provider hub with focus on a medical home;
- *Prevention and wellness reform*—changing from reactive to proactive health care delivery including focus on prevention and wellness, earlier detection of diseases, and supporting lifestyle changes; and
- *Performance measurement and health information technology (HIT) reform*—using measurements and electronic data in services delivery to improve quality outcomes.

Regardless of which specific provisions of federal health care legislation remain following political battles, it seems certain that laboratory medicine and pathology will undergo a transformation over the next several years. The fundamentals of these reforms have already begun, and will inevitably continue, on both private and government sides. The simple reason is that the system has reached the breaking point, and laboratory medicine must begin to prepare for these anticipated changes to the system. As there are a myriad of federal, state, and private market reform initiatives in various stages of piloting and implementation throughout the country, it may be tempting for lab directors and pathologists to take a "wait-and-see" approach before making any changes. G2 Intelligence suggests that this would be a mistake.

Recommendations

While the rate of reform infiltration varies by market, laboratories and pathologists must begin to prepare for inevitable market reform now. The call for action can be distilled down to efforts demonstrating and advancing the value of testing and services. G2's recommendations for laboratorians and pathologists are as follows:

1. Develop a test utilization program

A test utilization program codifies the expertise of the laboratorian or pathologist and translates that knowledge into clinical value and health care savings. These programs provide clinicians evidence and information to optimize ordering of tests, yielding improved quality of care and cost savings by avoiding unnecessary tests and preventing complications from frequently omitted testing, like pharmacog-

enomic testing of warfarin patients. Test utilization programs are in high demand by clinicians, the majority of whom recognize that they lack knowledge about the rapidly expanding menu of diagnostics testing. Many reform stakeholders, including payers and accountable care organizations (ACOs), have begun asking for utilization programs for molecular diagnostics, in particular.

Utilization programs require an evidence base, a laboratory information system (LIS) (preferably with connectivity to a hospital electronic health record (EHR) system), an analysis of clinician ordering patterns, and a means of communicating with clinicians. Outside consultants or vendor software packages can analyze test ordering patterns. Laboratories can market their test utilization programs to all stakeholders and reform organizations to demonstrate laboratory medicine's value, measured in quality and cost savings.

2. Provide consultative services for and routinely reach out to clinicians

Clinical consultative services involve laboratory professionals advising clinicians regarding diagnostic testing and diagnostic dilemmas in settings such as hospital rounds, morbidity and mortality meetings, inpatient admissions, and specialist consults. Consults might address the most appropriate tests to order for a particular patient situation or the development of an algorithmic protocol for conditions or situations for which a hospital experiences poor outcomes or high expenses. In addition, labs and pathology groups should establish routine outreach communications to physicians, hospitals, and even, perhaps, payer medical directors. These communications might take the form of educational presentations (e.g., webinars, breakfasts, or lunches), special reports (for example, with data regarding ordering trends, benchmarks, etc.), or clinic visits.

These services demonstrate expertise and clinical value. In a marketplace in which the currency is delivering health care value, laboratory professionals and pathologists must become information service providers whose expertise can improve quality and generate savings. Consultative services can demonstrate value applicable to cost avoidance and savings. These services need to be broadly and frequently marketed. During these years of dynamic market reform fluctuations, having relationships with local provider organizations will allow laboratorians to stay on top of plans and anticipate changes.

3. Develop a system for cost accounting and reduction

Cost accounting is nothing new for private laboratories that operate as for-profit businesses but poses challenges to hospital laboratories that often are not financially separated from the rest of the hospital. Nonetheless, the hospital lab must estimate all direct and indirect expense items—labor, supplies, equipment depreciation/rentals or leases, reference testing, repairs and maintenance, and overhead because ACOs and other payment reform initiatives require detailed assessments of costs. The more thoroughly and accurately a lab understands these costs, the less chance of losing money by having underbid a contract.

While many types of cost-reduction schemes are beyond the scope of this article, G2 recommends that a laboratory select an initiative that is also designed to improve quality, such as the Six Sigma and Lean programs. Implementation might be most quickly achieved by retaining a consultant, as the more rapid achievement of greater efficiencies would likely more than compensate for the expense of the consultant, and the lab would be prepared earlier for sudden regional changes.

4. Generate an 'evidence base' supporting your laboratory or pathology group's value proposition

The purpose of a laboratory or pathology group value proposition "evidence base" is to provide qualitative and quantitative data justifying the clinical benefit and

financial compensation appropriate for these services. Conceptually, this can be viewed as a portfolio to be used when interacting, negotiating, and advocating with the variety of market stakeholders including hospital administrators, ACO executives, health system executives, investors, provider organizations, and payers.

Laboratorians and pathologists should undergo a systematic inventory and analysis of their organization's certifications, awards, quality performance, efficiencies and costs, technologies and tests, and IT systems. Other relevant resources include professional societies' benchmarking data, published literature, quality metrics organizations, and hospital or client databases.

Included in such a compilation should be evidence of introducing or recommending lab tests or platforms that delivered measurable clinical and cost benefits including tests that improved the accuracy of diagnoses (reference published literature) and tests that shortened length of stay (either reference literature or use hospital before-and-after data).

5. Track and publish laboratory and pathology performance metrics

To be positioned as a highly valued knowledge provider who is integral to the clinical team, laboratorians and pathologists should begin sharing their quality performance indicators with clinicians and other stakeholders. Extending the scope of metrics beyond the more technical quality control-related error rates to include measures with more obvious clinical relevance would be very effective.

Transparency with the public, clinicians, and other market stakeholders regarding the laboratory's performance indicates an understanding and adoption of "the new rules of reform." This signals an organization that is striving for excellence and thus can differentiate the lab or group from the rest of the market. The optimal approach might be to design one's own quality program, including both industry metrics, as well as some custom performance indicators, possibly including pre-analytic performance indicators, analytic performance indicators, post-analytic performance indicators, and operational performance indicators.

6. Create a patient engagement program

Patient engagement refers to providers involving patients and their caregivers in all aspects of their care and empowering them through education and support to take on the management of their own care. Virtually all new care delivery and payment reform systems contain some element of patient engagement or patient centeredness. This might take the form of performance metrics, structural requirements, like the medical home, or other organizational design elements.

A laboratory patient engagement program can run the spectrum from patient-friendly lab reports to specialized educational services that can essentially represent a supplemental business line. Laboratory test data has been shown to be a powerful tool in engaging patients if delivered and presented optimally. Studies of patient portals found that access to lab results was patients' most popular feature and that it motivated healthy behavioral changes.[1]

The return on investment for a program such as this can come from either participation in the shared savings pool of an ACO or medical home (some patient-centered medical home (PCMH) models include a shared savings component), a service fee from the PCMH, a higher contract rate negotiated with a payer, or a private market joint venture that incorporates these offerings.

PCMHs are an optimal setting for laboratory patient engagement programs. Providers and payers are both seeking any and all tools and services that can involve

[1] Paul C. Tang and David Lansky, "The Missing Link: Bridging the Patient-Provider Health Information Gap," *Health Affairs*, 24, no. 5 (2005): 1290-1295; *http://content.healthaffairs.org/cgi/content/full/24/5/1290*

patients in their self-care and catalyze behavioral change. Generally, any reform initiative with a care management component requires patient engagement and would be receptive to laboratory support.

7. Offer specialized prevention and wellness testing services

The federal health care reform bill prohibited copays for a wide number of preventive services beginning in 2010 for many group health plans and in 2011 for Medicare. The adult preventive tests that fall under this provision and that will contribute to an increase in testing volume mostly screen for infections (especially sexually transmitted diseases), lipids, or diabetes.

Reform initiatives to integrate prevention and wellness programs into care delivery are becoming widespread and are universally supported by corporate America, private payers, and government organizations. The Patient Protection and Affordable Care Act (PPACA) created a $15 billion Prevention and Public Health Fund, administered over 10 years, to fund a multitude of programs. Overall, PPACA provides for three key prevention and wellness advancement platforms: (1) eliminating cost-sharing for clinical preventive services, (2) new funding for community preventive services, and (3) new funding for workplace wellness programs.[2]

G2 estimates that in 2012, approximately 20 million to 28 million more preventive laboratory tests might be performed nationally, representing an additional $275 million to $375 million in test revenue. In 2013, with the addition of Medicaid prevention benefits, an estimated 34 million to 47 million more preventive laboratory tests might be performed, representing $450 million to $610 million in revenue.

Thus, the prevention and wellness reform initiatives are not insignificant and represent a real opportunity for market differentiation or else for developing a new market niche or business line.

8. Invest in comprehensive health information technology systems

Powering many of the recommendations enumerated here and the reform initiatives taking place in the market are HIT systems with advanced functionality. Without electronic forms of health care data, providers cannot analyze costs and results, coordinate care, and manage patients across time and care settings.

Laboratories need to be ready to electronically deliver data and analytics in new ways to clinicians, administrators, and payers. Provider organizations are investing in HIT systems to power new payment and care delivery initiatives and are being incentivized to adopt electronic medical records (EMRs) and EHRs by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act).

The situation is fluid, in part given the phased implementation associated with the HITECH Act's "meaningful use" criteria. However, any laboratory or pathology group wanting to play an active role in an ACO should be able to interface with providers' EMRs and hospitals' EHRs. There are opportunities for laboratories to go beyond mere LIS connectivity and offer value-added information that supports other ACO IT needs with predictive analytics regarding clinical course and outcomes, clinical decision support, care management algorithms, and test utilization patterns.

Editor's note: This article is excerpted from an upcoming report from G2 Intelligence: Healthcare Market Reforms: Implications and Prescriptions for Laboratories. *The report will be available for purchase at* www.G2Intelligence.com.

[2] *Id.*

FTC Dismisses Challenge to Merger of LabCorp and Westcliff, *from page 1*

Appeals for the Ninth Circuit had granted a stay of the Feb. 22 order on March 4.

Originally, the FTC sought an injunction to prevent LabCorp from integrating the companies, pending the outcome of administrative litigation. After the U.S. District Court for the Central District of California denied a motion for injunctive relief, FTC appealed to the Ninth Circuit.

The December 2010 administrative complaint alleged that LabCorp's acquisition of Westcliff, which was completed in June 2010, would lead to higher prices and lower quality in the Southern California market for the sale of clinical laboratory testing services to physician groups. In addition, it claimed that the concentration would leave only two significant laboratories in Southern California competing to provide critical testing services to most physician groups.

Providers to Face Numerous ACO Compliance Issues

"ACOs must have a compliance program in place, and they must also have a conflict-of-interest policy that applies to members of the governing body."
– Michael Park

Providers looking to participate in proposed accountable care organizations (ACOs) will need to develop compliance programs as well as screen job applicants, according to Michael Park, an attorney with Alston & Bird in Washington.

"ACOs must have a compliance program in place, and they must also have a conflict-of-interest policy that applies to members of the governing body," Park said April 11 during the Health Care Compliance Association's 2011 Compliance Institute.

An ACO is a group of medical care providers that accepts responsibility for providing or arranging all care for a group of patients under a payment arrangement that allows it to profit from reducing costs and improving quality. The Centers for Medicare and Medicaid Services (CMS) released a proposed rule March 31 for implementing ACOs.

Park said the ACO proposed rule would require providers to:

- Have a designated compliance official, who cannot be the legal counsel;
- Have a mechanism for identifying and addressing compliance problems;
- Have a method for reporting suspected violations to appropriate law enforcement agencies; and
- Provide organizational compliance training.

"The ACO also has to maintain the ultimate responsibility for compliance with all the terms and conditions of its agreement," Park said. He also noted that CMS proposed a requirement to screen ACO applicants and is soliciting comments.

Increased Data Analysis

Park was joined at the session by Kimberly Brandt, chief health care investigative counsel for the Senate Finance Committee Republican staff and former director of CMS's program integrity group, who said that CMS is developing its data analytics capabilities.

"CMS has said that they'll begin using predictive modeling in all 50 states, starting this summer," Brandt said. "This will make the need for provider documentation critical. More and more claims will get kicked out in the front end, so organizations need to ensure that their documentation is accurate."

Data transparency is also a growing issue, Brandt said, including sharing data between the public and private sectors. "Over the next six to 12 months, there will be more work on data sharing," she said.

Brandt also said there will be increased congressional attention on the implementation of fraud and abuse provisions in the Patient Protection and Affordable Care Act (PPACA) including a close monitoring of new application fees, screening provisions, and suspension authority, although she indicated that Republicans are "more cautious" about using suspension authority. Brandt said that Congress would be looking to see what impact the new regulatory changes have on providers.

Lab Interoperability Initiative Accepting Hospital Applicants

The Lab Interoperability Cooperative (LIC), a federal initiative to link hospital laboratory facilities to federal health agencies, announced April 25 that it is seeking hospital participants.

The LIC will provide technical assistance to help hospitals submit electronic data on reportable laboratory results to appropriate public health agencies and is expected to connect at least 500 hospital labs, including critical-access or rural hospitals, with public health agencies over two years, according to an announcement from the cooperative.

Funded by the Centers for Disease Control and Prevention, the initiative is led by the American Hospital Association, the College of American Pathologists, and Surescripts, a provider of electronic prescribing networks.

According to the initiative's Web site, the LIC timeline consists of three main components: outreach and recruitment, which has been launched; functional interoperability and health information exchange; and implementation, which will include launching a small group of pilot labs throughout 2011 and early 2012.

By participating in the LIC initiative, hospitals could reach "meaningful use" goals for electronic health records (EHRs) more rapidly, having met the regulatory requirements for connectivity, according to the Web site.

Furthermore, participants would be equipped to address future public health and clinical laboratory reporting requirements as meaningful use initiatives evolve.

The Health Information Technology for Economic and Clinical Health (HITECH) Act, part of the American Recovery and Reinvestment Act (ARRA), authorized Medicare and Medicaid incentive payments for the adoption and meaningful use of certified EHR technology.

OIG Official Says Fraud, Abuse Law Waivers Likely to Be Applied Consistently to All ACOs

Proposed waivers of the physician self-referral law, federal anti-kickback statute, and civil monetary penalties law for qualified accountable care organizations (ACO) most likely would be applied consistently across all entities, a senior adviser with the Department of Health and Human Services Office of Inspector General said during an April 28 Web conference.

"We are not envisioning a case-by-case or advisory opinion approach for introducing the waivers; they would be consistent for everyone," Vicki L. Robinson said during a Health Care Compliance Association Webinar, Proposed ACO Rule: Risks & Challenges for Compliance Officers.

The Centers for Medicare and Medicaid Services (CMS) and OIG published in the April 7 *Federal Register* a notice with comment period pertaining to proposals for waivers of fraud and abuse laws for ACOs. Comments are due June 6.

Providers have expressed concerns that without fraud and abuse law waivers, the creation of ACOs would create financial relationships that could run afoul of existing laws. Robinson said any waivers to fraud and abuse laws would "supplement, not supplant, existing safe harbors and exceptions."

Under the OIG-CMS notice, the Stark, anti-kickback, and CMP laws would be waived with respect to the distribution of shared savings payments to ACOs, Robinson said. In addition, the anti-kickback and CMP laws would be waived for Stark-compliant relationships within the ACO, she said. The Stark law prohibits referrals of Medicare and Medicaid patients to entities with which physicians or their immediate family members have a financial relationship if the referral is for the furnishing of designated health services.

"Usually, arrangements that comply with the Stark law are still subject to the [anti-kickback] and CMP laws, so this would be a departure from the norm," Robinson said. "Our goal is to use the waiver to support ACOs while at the same time protecting patients. We want to ensure that the fraud and abuse laws do not impede beneficial ACOs."

ACOs also will need to implement and maintain a compliance plan and designate a compliance officer who is not the legal counsel. In addition, the compliance officer must have direct communication with the ACO's governing board.

Compliance Challenges

Robinson was joined on the Web conference by Max Reynolds, deputy general counsel of health law for the University of California Office of General Counsel. Reynolds said that compliance officers will face numerous challenges associated with implementing ACOs. For example, he said, ACO compliance officers must monitor their clinical operations to ensure that high-risk beneficiaries are not being denied service.

"It's very significant that you monitor whether you're avoiding high-risk beneficiaries and steering healthy beneficiaries into your network," Reynolds said. "Make sure that you're not doing anything to deter the high-risk beneficiaries from getting care."

A greater number of high-risk beneficiaries could reduce the shared savings payments for ACOs, Reynolds said. ACOs also will need to implement and maintain a compliance plan and designate a compliance officer who is not the legal counsel, he said. In addition, the compliance officer must have direct communication with the ACO's governing board.

Other compliance requirements include:

- Ensuring that the ACO adheres to the governing board structure in the original application to CMS;
- Ensuring that state licensing requirements are met;
- Validating the ongoing implementation of a quality assurance and improvement process, led by a physician;
- Allowing CMS to approve marketing materials before their use; and
- Notifying the Federal Trade Commission if there is a material change to the ACO network that gives it a market share of more than 50 percent.

News-At-A-Glance

MEDICARE TRANSPARENCY SOUGHT: Legislation introduced recently by a bipartisan pair of senators would seek to reduce Medicare fraud by opening Medicare claims data to public scrutiny for the first time in 30 years. The measure, (S. 756), co-sponsored by Sens. Chuck Grassley (R-Iowa) and Ron Wyden (D-Ore.), would require the Department of Health and Human Services, by the end of 2012, to establish a free, searchable, public database showing Medicare billing and payment records. "More transparency about billing and payments increases public understanding of where tax dollars go," Grassley said in a statement issued April 7, when the bill was introduced. "The bad actors might be dissuaded if they knew their actions were subject to the light of day." Release of Medicare payment data, identifiable by physician, has been prohibited since 1979 as a result of a federal court injunction in Florida. That decision said the data are protected under the Privacy Act of 1974, as well as a provision of the Freedom of Information Act that exempts certain personal information from public disclosure.

HOSPITALS OPPOSE STARK REPEAL: A group of hospital associations asked Congress April 6 to oppose two pending bills that would repeal all limits on physician self-referrals to physician-owned hospitals, according to a letter sent to members of Congress. "To be clear, community hospitals embrace fair competition where facilities compete over quality, price and patient satisfaction," the letter from the American Hospital Association, the Federation of American Hospitals, and the Coalition of Full Service Community Hospitals said. "However, we are strongly opposed to self-referral which skews the marketplace in favor of physician owners who self-refer the healthiest and wealthiest patients to their own facilities," the letter said. The physician self-referral law, or Stark law, prohibits doctors from referring Medicare and Medicaid patients to an entity in which they have a financial relationship, either through a direct investment or through a family member. Prior to the Patient Protection and Affordable Care Act (PPACA), physician-owned hospitals could be exempted from the Stark law if they provided services in a rural area or the physician investment was in the whole hospital, not a particular division.

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