G2 Compliance Report

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For Hospitals, Laboratories and Physician Practices

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Physicians Sue Over Illinois Billing Statute; New Law Prohibits Balance Billing by Pathologists, Others

Hospital-based pathology groups and physicians in Illinois filed a federal lawsuit on June 24, 2011, seeking to invalidate, on constitutional grounds, Illinois legislation designed to shift the burden of absorbing certain patient-related costs from insurers to practitioners of only a few specifically enumerated medical specialties.

Illinois Public Act 96-1523 took effect June 1, 2011. It amended portions of the Illinois Insurance Act in such a way as to fundamentally alter the relationships between certain physicians, their patients, and third-party payers, such as insurers, according to McDonald Hopkins, the law firm representing the physicians.

The statute prohibits an inexplicably singled-out group of out-of-network physician-providers from billing insured patients for anything other than the applicable deductible or copay that would apply if the provider were an in-network provider for that patient. According to the statute, the provider must seek any remaining amount due from the patient's insurer. In the event of a dispute as to the amount the insurer

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GAO Finds CMS Well Behind Projections For Instituting Fraud Detection Systems

The Centers for Medicare and Medicaid Services is well behind its timetable for fully implementing and using two fraud detection information technology systems, according to a Government Accountability Office report (GAO-11-475) released July 12.

CMS has made progress in implementation, but the two anti-fraud systems—the Integrated Data Repository (IDR) and One Program Integrity (One PI)—do not yet "provide all the data and functionality initially planned," GAO said.

For instance, although CMS planned for 639 program integrity analysts to be using One PI by the end of fiscal 2010, as of October 2010, less than 7 percent were actively using the portal and the tools, GAO said in its report, *Fraud Detection Systems: Centers for Medicare and Medicaid Services Needs to Ensure Widespread Use.*

CMS intended the IDR program to provide a single source of data related to the Medicare and Medicaid programs, the report said. One

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will pay, the statute mandates binding arbitration at the election of either the insurer or the physician.

By its terms, the statute applies only to those physicians or other providers who provide radiology, anesthesiology, pathology, neonatology, or emergency department services to insureds, beneficiaries, or enrollees in a participating facility or participating ambulatory surgical treatment center.

The statute originated as Illinois House Bill 5085, a bill intended to require certain insurance policies to provide coverage for certain oral cancer treatment drugs and for qualified individuals to participate in clinical cancer trials, as well as addressing other related issues. The bill was eventually passed out of both houses without substantial discussion following a single amendment on the floor of the Senate that entirely altered the bill to its present form, according to McDonald Hopkins.

"The statute, which after amendment was touted as an effort to relieve patients of the perceived administrative and financial burden of balance billing, actually does no such thing," says the firm in a statement on the case. "Regulations already in place had accomplished this goal some three years earlier. Rather, legislative history suggests that the statute actually act[s] to shift the economic burden from insurers, as set forth in these prior regulations, to a limited group of physicians."

The lawsuit, filed by Peoria Tazewell Pathology Group, Consultants in Clinical Pathology Ltd., Consultants in Laboratory Medicine and Pathology Ltd., Dr. Ronald Champagne, and Dr. R. Glenn Hessel, seeks to enjoin the state from enforcing the statute pending a final determination in the litigation. The plaintiffs also are asking that the statute be declared unconstitutional. G2

Owner of Detroit Clinic Sentenced to Prison For Her Role in a Testing Scam

An owner of a Detroit-area medical clinic has been sentenced to 15 months in prison for her role in a $1.12 million Medicare fraud scheme.

Maria Haber, 46, an owner of CompleteHealth LLC, also was sentenced by U.S. District Judge Patrick J. Duggan in the Eastern District of Michigan to three years of supervised release following her prison term and was ordered to pay $1,004,343 in restitution, jointly and severally with other defendants in the case.

Haber pleaded guilty on Oct. 27, 2010, to one count of conspiracy to commit health care fraud. She was one of 10 individuals charged in connection with a fraudulent diagnostic testing scheme operating at CompleteHealth and Ritecare LLC, another related clinic. Co-defendants Emilio Haber, Genna Yates, Alejandro Haber, Grant Johnson, Darrell Nichols, Elizabeth Egan, Hans Lobato, Emma King, and Melvin Young previously pleaded guilty to health care fraud conspiracy for their roles in the scheme.

According to court documents, Haber incorporated a limited liability company called CompleteHealth on Sept. 20, 2007, which purported to provide primary care services at a facility in Livonia, Mich. Haber signed the provider application submitted by CompleteHealth to enroll in the Medicare program and admitted that she helped operate the clinic.

Haber admitted that she and her co-conspirators, including her then-husband Emilio Haber, billed Medicare for medically unnecessary tests and services. Haber admitted in court documents that she obtained patients for CompleteHealth by paying kickbacks to driver recruiters and directly to Medicare beneficiaries. Haber

and her co-conspirators typically paid patient recruiters $100-$150 per patient, with $50-$75 going to the patient in exchange for visiting CompleteHealth and subjecting themselves to medically unnecessary tests.

According to court documents, Haber's co-conspirators instructed the patient recruiters to have the patients feign certain symptoms to justify the medically unnecessary tests. The kickbacks paid to the recruiters and the patients were contingent upon the Medicare beneficiaries identifying the symptoms necessary to justify the medically unnecessary tests reflected in the patients' medical records. The fraudulent conduct continued at Ritecare after CompleteHealth merged with it in June 2008.

The case was investigated by the FBI and Department of Health and Human Services Office of Inspector General and was brought as part of the Medicare Fraud Strike Force.

Since its inception in March 2007, the Medicare Fraud Strike Force's operations in nine districts have obtained indictments of 1,000 defendants that collectively have billed the Medicare program for more than $2.3 billion.

LabCorp to Pay $49.5 Million to Settle California Lawsuit

Laboratory Corporation of America Holdings (Burlington, N.C.) has agreed to pay the state of California $49.5 million to settle a lawsuit alleging that the company overcharged the state's Medicaid program (Medi-Cal) for clinical laboratory testing.

LabCorp disclosed the settlement in a July 14 filing with the Securities and Exchange Commission (SEC). The company had been scheduled to go to trial in January 2012. LabCorp says it agreed to the settlement to avoid the uncertainty and costs associated with prolonged litigation.

The company recorded a second-quarter pretax charge of $34.5 million (net of a previously recorded reserve of $15 million), $20.7 million after tax. The settlement is subject to a final negotiation and approval.

The lawsuit against LabCorp, Quest Diagnostics, and several other major labs operating in California was filed in 2005 under the state's False Claims Act by a competitor, Chris Riedel, chief executive officer of Hunter Laboratories (Campbell, Calif.). Under the act, the whistleblower can be rewarded with 15 percent to 25 percent of the amount recovered.

In 2009, the state attorney general's office joined the case, noting that under state law, "no provider shall charge [Medi-Cal] for any service . . . more than would have been charged for the same service . . . to other purchasers of comparable services . . . under comparable circumstances." The attorney general's office blasted what it called a pattern of abuse whereby the labs in the case charged Medi-Cal up to six times more for tests than it charged other customers, such as independent practice associations, physician offices, and hospitals.

The LabCorp settlement comes on the heels of a $241 million settlement with Quest Diagnostics (Madison, N.J.), announced in June, of allegations of lab overpricing of Medi-Cal over a 15-year period. Quest also agreed to price-reporting obligations for a limited time and, in lieu of such obligations for a transitional period, to provide Medi-Cal with a discount until the end of July 2012. In reaching a settlement, the company admitted no wrongdoing but sought to avoid the risk, time, and expense of lengthy litigation. As part of the recovery, Riedel reportedly received $70 million.

Seven others involved in the California case have either settled or been dropped from settlement discussions. In all, the lawsuit settlements have recovered roughly $300 million.

Riedel and his law firm Cotchett, Pitre & McCarthy have filed "lowest charge" lawsuits in six other states, according to *Laboratory Economics*: Florida, Georgia, Massachusetts, Michigan, Nevada, and Virginia.

Myriad Claims Victory in Ruling on Gene Patents

In a long-awaited decision, the Court of Appeals for the Federal Circuit ruled that genes can be patented, overturning a lower court decision that essentially invalidated Myriad Genetic's patents for its BRACAnalysis test.

In a 2-to-1 decision, the appeals court ruled the DNA isolated from the body was eligible for patents because it was "markedly different" in its chemical structure from DNA that exists inside the chromosomes in the body. As a result, isolated DNA is not simply a product of nature, which would not be eligible for a patent.

In another part of the ruling, the court ruled against Myriad's patent claims on the process of analyzing whether a patient's genes had mutations that raised the risk of cancer. The court said the process was not patentable because it involved only "patent-ineligible abstract mental steps."

The appeals court ruled the DNA isolated from the body was eligible for patents because it was "markedly different" in its chemical structure from DNA that exists inside the chromosomes in the body.

Myriad Genetics, based in Salt Lake City, applauded the court's ruling. "We strongly support the court's decision that DNA and cDNA are patent-eligible material as both are new chemical matter with important utilities which can only exist as the product of human ingenuity," said Peter Meldrum, president and CEO of Myriad. "Furthermore, we believe this decision is in the best interests of the agriculture, biotechnology, and pharmaceutical industries, as well as the hundreds of millions of people whose lives are bettered by the products these industries develop based on the promise of strong patent protection."

The ruling is in response to a lawsuit brought by a group of patients and scientists represented by the American Civil Liberties Union and Public Patent Foundation. In an opinion issued in March 2010, U.S. District Judge Robert Sweet ruled Myriad's patents on BRCA1 and BRCA2 were invalid, saying that isolated DNA was not really different from the DNA in the body.

But the appellate decision rejected Sweet's reasoning, saying that since DNA is a chemical, the chemical structure is what matters and that "informational content is irrelevant to that fact."

The ACLU called the latest ruling a blow to the idea that patent law cannot impede the free flow of ideas in scientific research. "Human DNA is not a manufactured invention, but a natural entity like air or water," said Chris Hansen, a staff attorney with the ACLU Speech, Privacy, and Technology Project. "To claim ownership of genetic information is to unnecessarily block the free exchange of ideas."

The decision also rejects arguments made by the Obama administration, which had filed a friend of the court brief arguing that isolated DNA should not be patented and that many of the gene patents issued by the U.S. Patent and Trademark Office are invalid.

Although the case could be appealed to the Supreme Court, industry analysts believe Myriad will maintain its patent-protected position for its BRACAnalysis test for some time.

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COMPLIANCE PERSPECTIVES

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A New Approach to Surveys: Building Quality From the Inside

In the first part of this article we examined the importance of building a culture of quality in laboratories and explored common themes of labs in trouble, from weak management to limited regulatory knowledge to reliance on outsiders for quality. Now that the depth and breadth of quality failures in the laboratory industry are better understood, what strategies exist for addressing them? Laboratorians are practical folks—they want answers, procedures, road maps, and checklists. The rest of this article offers some potential solutions, both practical and theoretical.

Strategy 1: Make Quality a Core Organizational Value

In the laboratory industry, quality must be viewed as a core organizational value. The challenge will be to transform from a reactive to a proactive culture, one in which quality is not a plan on the shelf or one of the things that we do, but the *way we do everything*. Most laboratories live in a crisis-oriented, reactive world. Think back to Stephen Covey's *The 7 Habits of Highly Effective People*.[1] He shares a simple but fundamental secret to success built on a time management matrix illustrated in the table on p. 6.

According to Covey, people spend their time in one of four ways:

1. Responding to things that are urgent and important (Quadrant I).
2. Working on preventive measures that are important but not urgent (Quadrant II).
3. Going through the motions of day-to-day activities, doing things that are not particularly important but may be urgent (Quadrant III).
4. Lost in trivia and busy work, doing activities that are neither important nor urgent (Quadrant IV).

Quality is a Quadrant II activity and requires a proactive approach. It is important but not urgent, so it takes discipline to make the time for it initially, but it ultimately pays off with results that prevent problems from occurring in the first place. Unless time is committed to building systems to prevent problems, laboratory managers will be forever stuck in crisis mode and feel beaten down each day. Many are caught up in the urgencies of day-to-day life (Quadrants I and III), precipitating a downward spiral and feeling out of control.

As a group, laboratorians can often be their own worst enemies. They are the quintessential "can do" people—no matter what is asked of them, they find a way to do it, usually without fanfare. This behavior is reminiscent of the parable of the boiled frog. If a frog is placed into boiling water, it will jump out immediately, knowing that it is in hot water both literally and figuratively. On the other hand, if it is put in cool water and the heat is slowly increased, the frog does not recognize the gradual change and stays in the water until it is boiled. Many laboratory managers today have been doing more with less for so long that they have become "boiled frogs."

[1] *Covey, S.R.* The 7 Habits of Highly Effective People. *New York: Simon & Schuster Inc.; 1989.*

Changes may be imperceptible over time, but cumulatively they can have dire consequences. Overwhelmed with day-to-day crises and urgencies, managers have lost the ability to know when things are out of control. They have lost their innate intolerance for poor quality and may lack the courage to ask for help. It is only by moving away from this pattern of reactive behavior and adopting a proactive philosophy of prevention that laboratory managers can ultimately regain control of their operations. By spending more time in Quadrant II activities, such as developing true quality systems, they will have fewer problems and more time to devise even better systems on a continuous basis going forward.

The Time Management Matrix

	URGENT	NOT URGENT
Important	**I** Crises Pressing problems Deadline-driven projects	**II** Prevention Relationship building Planning Recreation
Not Important	**III** Interruptions Some calls, mail, meetings Pressing matters Popular activities	**IV** Trivia, busy work Some mail, calls Time wasters Pleasant activities

Source: Covey, SR. The 7 Habits of Highly Effective People. *New York: Simon & Schuster Inc., 1989, p. 151. Reprinted by permission.*

Strategy 2: Develop a Quality Systems Approach

While the Centers for Medicare and Medicaid Services mandates a "quality systems approach" for the preanalytic, analytic, and post-analytic phases of the total testing process as well as general laboratory systems, it does not clearly define what is required. The terminology used can be confusing: "QA," for example. In Subpart K—"Quality Systems for Nonwaived Testing" of the Clinical Laboratory Improvement Amendments regulations and in various educational presentations from CMS spokespersons, the former "quality assurance" has been replaced with "quality assessment." The change in QA terminology is one example of how CMS is expanding its view of quality to a more systems-based approach. Three main statements in Part 493—Laboratory Requirements, Subpart K, Introduction (sec. 493.1200) provide a laboratory with the most guidance on what is required:[2]

a. Each laboratory that performs nonwaived testing **must establish and maintain written policies and procedures that implement and monitor quality systems** for all phases of the total testing process (that is, preanalytic, analytic, and post-analytic) as well as general laboratory systems.

b. The laboratory's quality systems **must include a quality assessment component that ensures continuous improvement** of the laboratory's performance and services through ongoing monitoring that identifies, evaluates, and resolves problems.

c. The various components of the laboratory's quality systems are used to meet the requirements in this part and **must be appropriate for the specialties and subspecialties of testing the laboratory performs, services it offers, and clients it serves.**

[2] *U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical Laboratory Improvement Amendments of 1988; Final Rule.* Federal Register. *1992 (Feb 28):7175 [42CFR493.1443]; see* ecfr.gpoaccess.gov/cgi/t/text/textidx?c=ecfr&tpl=/ecfrbrowse/Title42/42cfr493_main_02.tpl.

In interpreting these statements, the first steps a laboratory should take and document when developing a quality assessment plan are to:[3]

1. Identify who your customers are and what they need;
2. Develop a process to identify specific measurement indicators to assess if the customers' needs are being met;
3. Determine an acceptable range of performance for each indicator and how they are to be monitored; and
4. Implement a continual improvement process to address performance that is not acceptable, which includes assessing the effectiveness and sustainability of changes.

Whether the organization is refining an existing plan or starting from scratch, the single best resource is the Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS). CLSI produces consensus-based guidelines for medical laboratories. Its *Application of a Quality Management System Model for Laboratory Services; Approved Guideline–Third Edition* (GP26-A3) is a document that provides a model for medical laboratories for implementing and maintaining an effective quality-management system. The guideline describes 12 essentials that form the basic building blocks of a quality system.[4]

Strategy 3: Subscribe to a Benchmarking Program

If one benchmarks those laboratories that have been in regulatory trouble against a comparable peer group, they often look like top performers in terms of cost and productivity. This seems counterintuitive at first but makes sense when examined further. Too few staff may make a laboratory appear to be a "top performer" or off the charts (greater than the 100th percentile). This phenomenon necessitates re-evaluation of what is considered to be a top performer. When are the benchmarking numbers too good? At what point does the laboratory go from being highly productive to dangerously understaffed? The best way for a laboratory to know if it is understaffed is to subscribe to a benchmarking program that provides the relevant numbers to corroborate its claims. Use of this approach allowed one laboratory to convince hospital executives to add three FTEs during a time of budget shortfalls. The risks of quality noncompliance are too great, which is understood by every executive.

Strategy 4: Educate the Workforce

In order for everyone to "own" quality, they must be trained on the quality basics and held accountable for incorporating the concepts and tools into their daily activities.

With the average age of laboratory technologists in the 50s, the majority of the technical workforce may have a narrow view of quality, focusing on quality control instead of quality assurance and regulatory compliance. It is recommended that quality and regulatory training be incorporated into new employee orientation and also be made a part of the annual skills competency program for all employees.

It is essential for anyone in a leadership position to be skilled in process improvement. At minimum, each organization should identify and train its leaders in a common improvement approach such as PDCA, Lean Six Sigma, or an internally defined methodology to ensure utilization of an organized and systematic approach.[5]

Regulatory knowledge is also essential for each leader, as it must guide many of their actions. While most laboratories look to one individual to be the internal "expert" on CLIA regulations, everyone must be held accountable for understanding

[3] *Laessig R.H., Ehrmeyer S.S.* New Poor Man's (Person's) Guide to Meeting the Regulations. *Madison, Wis.; R & S Consultants, November 2008.*

[4] *Clinical and Laboratory Standards Institute (CLSI).* Application of a Quality Management System Model for Laboratory Services; Approved Guideline–Third Edition. *CLSI document GP26-A3. Wayne, Pa.: Clinical and Laboratory Standards Institute; 2004.*

[5] *Ambrose, C., Daley, A. "How Do Your Quality Initiatives Measure Up?"* Clinical Leadership & Management Review. *2009; 23, no. 2: E1-E10.*

the expectations and ensuring that all activities within the preanalytic, analytic, and post-analytic processes are compliant. Annual review of regulatory changes and what to do when the CMS inspector arrives are necessary steps in maintaining an inspection-ready environment.

Strategy 5: Hold People Accountable

For quality to be truly integrated into the fabric of an organization, everyone has to understand it and be accountable for performing it in a manner consistent with quality ideals. The CLIA laboratory director or medical director can delegate responsibility to a quality manager, but he or she retains quality oversight responsibility and must ensure that quality functions are maintained. Delegation is not abdication. Technical managers should also have quality management as a key job responsibility, and if the administrative director does not have a technical background, the medical director has to work doubly hard to ensure compliance.

One way to develop a culture of quality is to measure progress, holding staff accountable for achieving performance metrics on a group as well as on an individual level. Quality should be a part of every meeting, communication, and performance evaluation. With time and practice, quality concepts will become part of the laboratory's culture. Transformations of this type are complex and commonly take three to five years.

Strategy 6: Be Inspection-Ready at All Times

Many laboratories prepare for inspections. They can predict the general window of time of regularly scheduled inspections by accrediting agencies and spend a few weeks or months prior to the inspection reviewing policies and procedures, discarding outdated reagents, and training staff. The expectation is that the inspection will occur during normal business hours. However, with CMS now conducting unannounced inspections as well as validation inspections in follow-up to visits by accrediting agencies with "deemed status," this reactive approach is no longer acceptable. (One can argue that it never was.)

Shifting to a proactive state of inspection readiness at all times represents a significant cultural change. It allows laboratories to be ready for unannounced inspections and for "preparation" to be an ongoing function that takes place throughout the year. Periodic internal audits will likely be needed to ensure ongoing readiness. If a laboratory has a true commitment to quality, this is the only approach that will ensure that the focus is on everyday operations rather than just passing an inspection.

Hospital laboratories are a 24-hours-a-day, seven-days-a-week operation. Since inspectors can interview staff on any shift, it is important to educate and train staff on all shifts and days of the week. One suggestion is to hold "survey drills" so it does not matter who is at work when inspectors arrive—everyone will be familiar with the process and know how to act. Many laboratories have policies that outline what to do when an inspector arrives as well as the most common questions that may be asked; this is a helpful tool not only for reducing stress associated with an inspection but also for ensuring all employees respond in a consistent manner.

Conclusion

The goal of this article has been to help raise awareness about laboratory quality on multiple levels. Health care is far behind other industries when it comes to incorporating quality-management systems into their daily operations. More importantly, laboratories are largely reactive, relying on outside accrediting agencies to inspect quality rather than developing internal assessment processes to ensure quality on an ongoing basis. The good news is that the most common deficiencies are easily preventable with effective quality systems.

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GAO Finds CMS Well Behind Projections, *from page 1*

PI is a Web-based portal and suite of analytical software tools designed to extract data from IDR and enable complex analyses of the information.

CMS initiated the two information technology system programs to integrate claims data and improve its ability to detect fraud, waste, and abuse in the Medicare and Medicaid programs, which the agency administers, GAO said.

Improper payments to the two programs were estimated to amount to about $70 billion in fiscal year 2010, GAO said. Although One PI officials have said the program could result in $21 million in savings over the nine-year life cycle of the project, GAO said not enough data are available to measure this estimate.

IDR has been operational since 2006, but it does not include all the data that were planned to be incorporated by fiscal year 2010. "For example, IDR includes most types of Medicare claims data, but not the Medicaid data needed to help analysts detect improper payments of Medicaid claims," GAO said. "IDR also does not include data from other CMS systems that are needed to help analysts prevent improper payments, such as information about claims at the time they are filed and being processed."

CMS program officials told GAO that these data are not incorporated because of technical obstacles and delays in funding, the report said.

GAO Recommendations

To help ensure that the development and implementation of IDR and One PI are successful, GAO recommended that CMS take the following steps:

- Finalize plans and develop schedules for incorporating data into the IDR that identify all resources and activities needed to complete tasks;
- Implement plans for incorporating data in IDR to meet schedule milestones;
- Establish plans and reliable schedules for training all program integrity analysts intended to use One PI;
- Establish and communicate deadlines for program integrity contractors to complete training on One PI;
- Conduct training in accordance with established deadlines;
- Define reasonable financial benefits expected of implementation of the two programs; and
- With stakeholder help, establish measurable, outcome-based performance measures for IDR and One PI that gauge progress toward meeting program goals.

In written comments on a draft of the report, CMS said it concurred with GAO's recommendations and the agency identified steps it was taking to implement them. The GAO report is available at *http://www.gao.gov/new.items/d11475.pdf.*

FDA Issues Draft Guidance on In Vitro Companion Diagnostics

The Food and Drug Administration (FDA) is proposing that in vitro diagnostic devices and the corresponding therapeutic products be approved or cleared contemporaneously for the use indicated in the therapeutic product labeling.

In a much-anticipated draft guidance announced July 12, the agency clarifies FDA's definition of a companion diagnostic, recommends early engagement between the FDA and manufacturers so that the agency's expectations are included in development plans, and highlights the FDA's intention to conduct simultaneous reviews of a drug or biologic therapy and its corresponding companion diagnostic.

The guidance also identifies instances where the FDA may approve a targeted medicine in the absence of a cleared or approved companion diagnostic. In cases where the therapy is intended to treat a serious or life-threatening disease or condition for which there is no available satisfactory treatment and when the potential benefits outweigh the risks of not having a cleared or approved companion diagnostic, the therapy could be approved first while the companion diagnostic may be approved or cleared later through the appropriate device submission process.

Ideally, according to the FDA, a "therapeutic product and its corresponding IVD companion diagnostic device would be developed contemporaneously."

The FDA defines an IVD companion diagnostic device as an in vitro diagnostic device that provides information that is essential for the safe and effective use of a corresponding therapeutic product. The use of an IVD companion diagnostic device with a particular therapeutic product is stipulated in the instructions for use in the labeling of both the diagnostic device and the corresponding therapeutic product, as well as in the labeling of any generic equivalents of the therapeutic product.

An IVD companion diagnostic device could be essential for the safe and effective use of a corresponding therapeutic product to:

- Identify patients who are most likely to benefit from a particular therapeutic product;
- Identify patients likely to be at increased risk for serious adverse reactions as a result of treatment with a particular therapeutic product; and
- Monitor response to treatment for the purpose of adjusting treatment (e.g., schedule, dose, discontinuation) to achieve improved safety or effectiveness.

FDA does not include in this definition clinical laboratory tests intended to provide information that is useful to the physician regarding the use of a therapeutic product but that are not a determining factor in the safe and effective use of the product.

Ideally, according to the FDA, a "therapeutic product and its corresponding IVD companion diagnostic device would be developed contemporaneously, with the clinical performance and clinical significance of the IVD companion diagnostic devices established using data from the clinical development program of the corresponding therapeutic product." However, the FDA states that it recognizes that this will not always be possible.

The guidance also notes that studies of companion diagnostics generally will be significant-risk devices that will require an investigational device exemption (IDE). Most studies of other IVDs are non-significant-risk.

FDA will use a risk-based approach to regulate companion diagnostics. FDA says that in its experience to date, companion diagnostics generally will be Class III devices requiring a premarket approval, but there could be instances where a 510(k) would be sufficient.

The guidance has been long-awaited by industry, which has sought guidance in this area marked by ambiguity, notes Jamie Wolszon, an attorney with Hyman, Phelps & McNamara (Washington, D.C.) on the FDA Law Blog *(www.fdalawblog.net)*. Years ago, the FDA issued a draft guidance on the topic, which received criticism from the industry. FDA stated last year that it would promulgate two guidances to provide clarity that would address issues including when the FDA would require simultaneous approval and what data would be required.

Comments on the draft guidance will be accepted until Sept. 12, 2011. The guidance is available online at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm262292.htm.*

Supreme Court Puts Crime Labs on Notice

In a 5-4 decision released June 23, the Supreme Court ruled that a man convicted of drunken driving was denied his right to confront witnesses against him when a lower court allowed, and higher state courts upheld, testimony on a blood test by a surrogate for the lab analyst who performed the test.

The question in *Bullcoming v. New Mexico* was whether the Sixth Amendment permits the prosecution to introduce a forensic lab report containing a testimonial certification—made for the purpose of proving a particular fact—through the in-court testimony of a scientist who did not sign the certification or perform or observe the test.

Writing for the majority, Justice Ruth Bader Ginsburg said, "Surrogate testimony of that order does not meet the constitutional requirement. The accused's right is to be confronted with the analyst who made the certification, unless that witness is unavailable at trial but the accused had an opportunity, pretrial, to cross-examine that particular scientist."

Background of the Case

Donald Bullcoming was arrested on charges of driving while intoxicated (DWI). He refused to take a breath test, so the police obtained a warrant to draw blood for alcohol analysis. The main evidence against him was a crime lab report certifying that his blood-alcohol concentration (BAC) was well above the threshold for aggravated DWI, a more serious crime.

On the day of trial, the prosecution said Curtis Caylor, the analyst who performed the test, "had very recently been put on unpaid leave" (but did not claim that he was unavailable to testify). Over the objection of the defense, the trial judge admitted the BAC report as a "business record" and the prosecution called Gerasimus Ratazos, another analyst who was familiar with the lab's testing procedures but had neither participated in nor observed the test on Bullcoming's blood sample.

The jury convicted Bullcoming and both the New Mexico Court of Appeals and the state's Supreme Court affirmed the conviction, finding that while the report qualified as testimonial evidence, its admission did not violate his right to confront witnesses against him because Caylor was a "mere scrivener," certifying machine-run results, and Ratazos qualified as an expert witness with regard to the testing machine and procedures.

Overruling the Lower Courts

In rejecting the reasoning of the New Mexico Supreme Court, Ginsburg said that "Caylor's certification reported more than a machine-generated number," including certifying the chain of custody, the integrity of the specimen, and the validity of the analysis. Operation of gas chromatography machines to determine BAC levels requires specialized knowledge and training, several steps are involved in the process, and human error can occur at each step. "Representations, relating to past events and human actions not revealed in raw, machine-generated data, are meet for cross-examination."

The ruling in *Bullcoming v. New Mexico* is in line with the high court's decision two years ago in *Melendez-Diaz v. Massachusetts*, Ginsburg noted. In that case, where the justices split 5-4 along similar lines, the court held that a forensic lab report stating that a suspect substance was cocaine ranked as a testimonial and could not be introduced by the prosecution without offering a live witness competent to testify to the truth of the statements in the report. In light of the Supreme Court decision, the case goes back to state courts to determine whether Bullcoming's conviction will stand. G2

News-At-A-Glance

RAC RECOVERIES GROWING: The Medicare Recovery Audit Contractor (RAC) program has collected $575 million in overpayments through June 2011, according to a report from the Centers for Medicare and Medicaid Services (CMS) released in July. The report examined overpayment collections from October 2009, when the RAC program was expanded nationally, through June 2011. The program is responsible for identifying and recovering improper Medicare payments. RAC overpayment collections have grown steadily in fiscal year 2011, from $81 million for the first quarter to $233 million for the third quarter. Initially the RAC program focused on the Medicare fee-for-service programs (Parts A and B). The recovery program will expand to the Medicaid program by the end of 2011, as well as to Medicare Part C (managed care) and Part D (the outpatient drug benefit). In addition to the recovered overpayments, the report found that RACs have returned $110 million in Medicare underpayments to providers since October 2009, more than double the amount ($52 million) included in the CMS RAC report from April. The CMS report is at *www.cms.gov/Recovery-Audit-Program/Downloads/NatProg.pdf.*

EHR ADOPTERS INCORPORATING LAB RESULTS: Of the 2,300 "early adopter" physicians that have attested to meeting the Stage 1 criteria for the electronic health record (EHR) "meaningful use" incentive programs, over 2,200 have done so successfully, officials with the Centers for Medicare and Medicaid Services (CMS) told the Office of the National Coordinator for Health Information Technology's Policy Committee Aug. 3. Additionally, 100 hospitals have attested successfully to the Stage 1 criteria for certified electronic health records. Currently, almost $400 million in Medicare and Medicaid incentives for meaningful use of EHRs have been paid in total, and the top two most common specialties receiving payments are family practice physicians and internal medicine physicians. Within the Stage 1 menu set criteria, physicians are choosing to use drug formulary checks and are incorporating laboratory test results and patient lists into EHRs, more than the other menu set criteria.

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