G-2 Compliance Report

WASHINGTON G-2 REPORTS

Issue 09-10/Nov.-Dec. 2009

For Hospitals, Laboratories and Physician Practices

FDA Focusing on Outliers in LDT Oversight

The Food and Drug Administration (FDA) is less concerned with traditional laboratories that develop their own tests than it is with a small number of "outliers" that game the system to escape FDA oversight, according to Don St. Pierre, deputy director of the agency's office of in vitro diagnostic device evaluation and safety.

St. Pierre, who spoke at Washington G-2 Reports' Lab Institute Sept. 24, reiterated the FDA's longstanding position that it has jurisdiction over laboratory-developed tests (LDTs) as a medical device. "If a lab makes an LDT, then it is a medical device manufacturer. Just because you have a CLIA certificate does not mean you are not a medical device maker, and everything you do is under FDA enforcement discretion."

The agency has used this discretion for most LDTs, St. Pierre noted. It currently regulates analyte-specific reagents (ASRs) used in LDTs and has issued guidance for a category of genetic tests, in vitro diagnostic multivariate index assays (IVDMIAs), which use a proprietary algorithm to produce a patient-specific result.

FDA's current policy on oversight of LDTs could change, but it would not be done quickly and not without open discussions with stakeholders, St. Pierre added. *Continued on page 2*

New Rules Designed to Protect Patients' Genetic Information

Individuals' genetic information will have greater protection through new regulations issued Oct. 1 by the departments of Health and Human Services (HHS), Labor, and the Treasury.

The interim final and temporary rules implementing sections 101 through 103 of the Genetic Information Nondiscrimination Act of 2008 are designed to help ensure that genetic information is not used adversely in determining health care coverage and will encourage more individuals to participate in genetic testing, which can help better identify and prevent certain illnesses.

HHS' Office for Civil Rights also issued proposed rules that would modify the Health Insurance Portability and Accountability Act (HIPAA) of 1996's privacy rule pursuant to GINA Title I to clarify that genetic information is health information. The proposed rule, published Oct. 7 in the *Federal Register*, also would prohibit the use and disclosure of genetic information *Continued on page 9*

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LDT Oversight, *from page 1*

FDA Focused on Proving Claims Made

In a follow-up panel discussion, St. Pierre stressed the bulk of his unit's workload is on the labeling of products and the claims made for them. "If you are offering an LDT that is truly an LDT, be sure you have good data to back up the claims you make in promoting it," he advised.

He also was asked about the petitions pending to change the two-tiered regulatory framework. Genentech and the Advanced Medical Technology Association (AdvaMed) have asked the FDA to subject LDTs to the same scientific and regulatory standards applied to test kits, thus leveling the playing field. A number of other groups have joined in support of the petitions.

"It is great that we have the petitions to begin to make decisions on the issues," he said. "They provide a mechanism to address the issues." He would not speculate on the time frame for any response, only noting that there is not time to have an open process and reach a decision this year. Moreover, the final call will be made at a level higher than his unit, he added.

Disputing FDA Oversight Claims

The FDA's claim to have jurisdiction over medical devices is a fundamental premise disputed by the American Clinical Laboratory Association (ACLA) and is an unresolved legal issue, said panelist David Mongillo, vice president for policy and medical affairs. LDTs are developed in-house for use only by that lab and the results are sold as a service, not marketed as a test kit, he said.

LDTs are of significant value in improving patient outcomes in clinical practice today, he said, comprising thousands of tests done daily on patients ranging from molecular diagnostics to guide treatment and therapy to modified test kits to detect common disease conditions.

"While the preponderance of LDTs present relatively low risk to patients, the increasing use and complexity of some LDTs underscores the need for increased oversight,"
— Jared N. Schwartz, M.D., Ph.D., CAP

ACLA contends that CLIA regulations along with standards of accrediting bodies are sufficient to ensure quality of LDTs. If there are issues regarding clinical validity, they should be addressed through CLIA, Mongillo said, "and if necessary, strengthen the bar but do not add another layer of federal oversight, given how tightly regulated the industry already is."

Change in the Equation

In the era of personalized medicine, there has been a profound shift in the weight given to laboratory testing in screening and diagnosis, observed panelist Laura van't Veer, Ph.D., chief research officer at Agendia, and head of molecular pathology at Netherlands Cancer Institute.

It has gone from being one of many components in medical decisionmaking to now having a central role, she said, and as a result, more rigorous studies are needed of the analytic and clinical validity and clinical utility of LDTs so that the information can be integrated into a result tailored to a patient's genetic profile.

Because of the increasing complexity of genetic testing, there is a place for FDA review, she concluded, but alongside CLIA, the Centers for Disease Control and Prevention, and other involved parties. "Our discussion should always be about what is the best way to assure quality test results for the patient."

CAP Proposes Risk-Based Oversight

Separately, in a Sept. 24 announcement, the College of American Pathologists (CAP) recommended a three-tier risk-based approach to regulating LDTs, defined

as medical tests performed by the laboratory in which the test was developed, and the test is neither FDA-cleared nor FDA-approved.

The proposed changes would encompass claims of clinical validity and specify scientific and regulatory standards to be applied to all LDTs. The risk-based classification would be divided into three categories—low, moderate, and high. The ranking would be based on claims made for the test, the potential risk to patients, and the extent to which results could be used in the determination of diagnosis or treatment.

"While the preponderance of LDTs present relatively low risk to patients, the increasing use and complexity of some LDTs underscores the need for increased oversight," said CAP President Jared N. Schwartz, M.D., Ph.D., in a statement. "CAP's risk-based model employs a public-private partnership to address oversight of these tests in an inclusive, systematic way."

In addition, CAP recommends strengthening CLIA accreditation standards on labs using low- and moderate-risk LDTs and requiring FDA review of all high-risk LDTs. CAP said the FDA should continue to exercise enforcement discretion in regulating LDTs, asserting authority only in specific instances where regulators believe implementation of an LDT without direct FDA oversight is not appropriate.

Finance Reform Package Would Target Enforcement, Penalties

The $856 billion health care reform bill approved by the Senate Finance Committee Oct. 13 contains several provisions aimed at curbing fraud and abuse in the Medicare and Medicaid programs, including a requirement that all providers adopt compliance programs and new and increased penalties for violations.

The package, which Finance Committee members began considering in September, also would increase by $100 million the Health Care Fraud and Abuse Control fund—the primary funding source for Medicare program integrity and anti-fraud efforts at the Department of Health and Human Services (HHS) and the Department of Justice (DOJ).

The proposal was released Sept. 16 by Finance Committee Chairman Max Baucus (D-Mont.). In addition to the fraud, waste, and abuse provisions in Title V of the bill, the reform package would require individuals to have health insurance coverage, establish a health care exchange market, reform the private insurance system, expand Medicaid, and establish state-based insurance cooperatives to compete with private plans.

The initial proposal from Baucus would pay for reform initiatives largely through Medicare and Medicaid spending cuts over 10 years, a tax on high-cost insurance plans, new fees on certain providers and suppliers, and other provisions.

More Provider Screening

Among ways the bill seeks to improve oversight of federal health programs is to require that the Centers for Medicare and Medicaid Services (CMS) more closely screen all Medicare providers and suppliers and give states the authority to conduct similar checks of Medicaid providers.

At a minimum, the bill would require that license checks be part of the Medicare provider and supplier approval process. However, additional screening efforts could include the requirement that providers submit fingerprints, criminal background checks, and random or unannounced site visits.

Medicare providers and suppliers would be required to pay a $350 application fee to cover the costs of the screening. The requirements would apply to existing Medicare providers, not just new ones. The bill would allow for a reduced screening fee of $250 for current providers if they paid within 12 months of enactment. A hardship exception to the fee would be permitted, as would waiver of the fee for Medicaid providers for whom the state can demonstrate the fee would impede beneficiary access to care.

The provision would give states the ability to conduct similar screening procedures for Medicaid providers and suppliers, and states that did not conduct such activities would lose a portion of the Federal Medicaid Assistance Percentage.

Beneficiary Sanctions

In addition to new and increased penalties for providers, the bill would give the HHS secretary the ability to establish administrative remedies for beneficiaries who knowingly participate in health care fraud schemes.

For providers and suppliers, the civil monetary penalty (CMP) law would be amended to add and increase CMPs for false claims, failures by hospitals to report adverse actions affecting physicians' clinical privileges, and for Part D and Medicare Advantage plans that falsify information and commit marketing violations.

The bill also would give the HHS secretary authority to establish a self-disclosure protocol for providers to report actual or potential violations of the physician self-referral law. The protocol for reporting such violations would be similar to the HHS Office of Inspector General's existing self-disclosure protocol and would apply to violations of the Stark law and anti-kickback statute that were less than $50,000.

The bill further seeks to require providers and suppliers to implement compliance programs as part of the Medicare and Medicaid conditions of participation. To qualify, compliance plans would be required to incorporate certain elements defined by the secretary. Also under the anti-fraud provisions, the bill would extend the recovery audit contractor (RAC) program to the Medicare Advantage and Part D programs.

Data Matching

Enforcement activities by HHS and other federal agencies would be enhanced under the bill by requiring CMS to complete development of the so-called One PI Integrated Data Repository.

CMS has begun including Medicare and Medicaid claims and payment data into the One PI system, and the bill would require the integration of similar data from other federal health care programs and enforcement agencies, including the Department of Veterans Affairs and DOJ. The bill would give the OIG and DOJ authority to use data in One PI to identify and investigate fraud and abuse cases.

The bill also would require that HHS expand existing provider databases and consolidate those databases into a centralized sanctions data system that would include national data on patient abuse and neglect cases. In addition to Medicare data, states would be required to submit Medicaid data from their Medicaid Management Information Systems.

The chairman's mark and recent amendments to the Finance Committee proposal are available at *www.finance.senate.gov*.

COMPLIANCE PERSPECTIVES

Judith Yost is director of the Division of Laboratory Services at the Centers for Medicare and Medicaid Services

The Good, the Bad, and the Ugly About Proficiency Testing Under CLIA

This article will delve into the details regarding the educational value of proficiency testing (PT) and the Centers for Medicare and Medicaid Services' (CMS) oversight of PT under the 1992 Clinical Laboratory Improvement Amendments (CLIA) regulations. It is intended to provide the reader sufficient information, hints, tips, resources, and guidance to ensure regulatory compliance and to prevent untoward PT events wherever possible. It is also designed to relieve some of the current anxiety in the laboratory community and to mitigate the negative publicity about CMS and its administration of CLIA PT requirements. In addition, a peek into the future of PT regulation will be included.

Since PT referral has become highly visible recently, it is also the goal of this article to reassure readers that these occurrences are not frequently identified and can be avoided with a little bit of effort and education on the part of the laboratory and its staff and management.

How Did We Get Here?

The ultimate design, development, and implementation of CLIA is not rocket science. CLIA is essentially modeled after basic oversight requirements or licensure programs, laboratory professional standards, and good laboratory practices that existed long before the law did. Because CLIA is a federally administered program, however, it must encompass input from the public prior to becoming final and must contain a balance of burden for the regulated entities so that the program ensures quality testing while making sure that regulated entities are not so overcome with requirements that they diminish the availability of testing to their patients and clients.

So as Congress deliberated in the 1980s about CLIA and the need for oversight by the Department of Health and Human Services (HHS) of all entities that conduct testing on human specimens for health purposes, lawmakers learned about an external outcome measure of testing accuracy that could become one of the key CLIA quality standards since it is a measure of how well the laboratory performs. And indeed, some laboratories were already utilizing proficiency testing at that time as an educational tool and a mechanism to accomplish continuous quality improvement. Sometimes PT has been referred to as the "backbone of CLIA."

But Congress soon realized that it would be easy for labs to "cheat" the system in PT and use a neighboring high-quality laboratory to test PT samples and then report their PT results as their own. With this in mind, lawmakers proceeded to write into the CLIA law the most stringent, mandatory penalties for this cheating because they believed strongly that if a laboratory would cheat on its PT performance, then it would have no qualms with misrepresenting its patient test results.

These penalties imposed by Congress include automatic revocation of the laboratory's CLIA certificate for one year, accompanied by a loss of Medicare payment; that the laboratory's director cannot direct a laboratory for two years; and that the name of the director and the laboratory will appear on CMS' Annual Laboratory Registry with those entities that have had sanctions imposed during the previous year. This registry and all prior registries reside on the CMS CLIA Web site. Thus, to avoid these serious penalties, laboratories should not send PT samples or a part of a sample to another laboratory for testing, nor should they communicate about PT results prior to the closure of the PT event.

We strongly caution you to encourage the development of robust PT policies and training to prevent any perception of "miscommunication" about PT results. Legally, inappropriate PT communication can be construed as PT referral.

Because the law is so clear and straightforward on this subject, in every case where a laboratory appealed this finding, CMS has prevailed. The ultracurious or legal folks can find a comprehensive listing of all previous PT referral administrative law judge (ALJ) and Department Appeals Board (DAB) cases and their outcomes on the CMS CLIA Web site. But better yet, there are interpretive guidelines and a CLIA PT brochure on the Web site with guidance about how to enroll and perform PT successfully and *not* be inadvertently caught in a PT referral situation.

Congress also mandated, due to PT's value as an educational tool, that all laboratories performing certain tests must annually enroll in a CMS-approved PT program for the primary test method utilized by the laboratory for these "regulated" tests and perform them successfully. The regulations also require that when laboratories receive a PT grade that is less than 100 percent, including clerical errors, they must investigate the cause of the failure and correct the problem to prevent reoccurrences. By doing this, laboratories can learn about "root causes" and improve systems and processes. The details of those requirements are incorporated into the 1992 CLIA regulations promulgated by CMS. The regulations for PT at 42 C.F.R. Part 493, Subpart H, can be linked from the CMS CLIA Web site, which is listed as a resource at the end of this article. The list of CMS-approved PT programs is also there.

Why Are We Here?

Why all of a sudden are these PT referral cases in the laboratory newsletters? Well, Congress never contemplated concepts like reflex testing, distributed testing, confirmatory testing, and so on. Some PT protocols even *require* the transfer of samples. Yes, Virginia, the world has changed since then—and my, has it changed! As a result, it is harder for laboratories to easily distinguish between what they do routinely with their patient specimens and how they handle their PT samples.

Another dramatic change is the evolving manner in which health systems array themselves (i.e., with one or more certificates in the same system with multiple testing sites, which also can lead to misuse of PT samples if not carefully addressed when reorganizations and mergers transpire). Remember CLIA PT is "by certificate." CMS and the state agencies that conduct CLIA surveys for CMS will gladly assist laboratories with any type of certificate questions.

And for those laboratories that are fortunate enough to acquire a quality assurance (QA) officer, PT coordinator, common technical supervisor, or other such positions that transcend testing sites, there is further risk of inappropriate PT communication.

So we strongly caution you to encourage the development of robust PT policies and training to prevent any perception of "miscommunication" about PT results. Legally, inappropriate PT communication can be construed as PT referral.

CMS is fully aware of these circumstances where "accidental" transfer of specimens may occur, and because we are so sensitive to the stringency of the potential enforcement actions, we have convened a team of experts in CMS' central office to carefully review each case that comes to light. In some instances sufficient facts were present for us to determine that the referral was inadvertent and the laboratory was not attempting to cheat. In these situations the most egregious penalties are not imposed. These CMS reviews will enable CMS to develop improved policy and standards for the future. So the important messages to the reader are that a determination of PT referral by CMS is not always automatic, mandatory sanctions are only imposed when warranted, and very few actual PT referral cases occur.

The "Proficiency Testing" brochure is available on the CMS CLIA Web site at www.cms.hhs.gov/clia/

We recently sent a letter to every laboratory director of nonwaived laboratories with key PT information and educational materials to share with the folks who actually work with PT samples to facilitate prevention of referral. Just like all other aspects of laboratory management under CLIA, it is the laboratory director's responsibility to promote awareness and knowledge to assist in performance of duties relative to CLIA compliance.

How to Avoid PT Referral

- ✓ Learn the CLIA PT regulations
- ✓ Be cautious with reflex, confirmatory, distributed testing, consultations
- ✓ Don't send PT samples or parts of samples to another laboratory
- ✓ Review internal processes to ensure maximum integrity and develop fail-safes
- ✓ Enroll in PT by CLIA certificate number for all regulated analytes
- ✓ Avoid interlaboratory communication until after the close of a PT event
- ✓ Report to CMS any sample you receive from another laboratory
- ✓ Call CMS if you inadvertently send a PT sample to another laboratory
- ✓ PT referral includes nonregulated analytes if a CMS PT program is used
- ✓ Train, train, train!

More information is available at www.cms.hhs.gov/clia/

But do not rest on your laurels or relax your vigilance: The need for knowledge and understanding of the regulations, periodic and focused staff training, top management support, and constant monitoring are critical to your efforts in precluding this circumstance in your laboratory permanently.

Therefore, if you find that your laboratory accidentally transported a PT sample to another laboratory, call that laboratory immediately, notify your local CMS representative, and retain all relevant documentation. Conversely, if your laboratory receives a PT sample for testing from another laboratory, notify CMS as well. Contacts are listed on the CMS CLIA Web site under enrollment.

The Good, Better, Best!

CMS and deemed accrediting organizations monitor PT performance regularly for their constituent laboratories, not just at the time of survey, and will contact the laboratory when failures in performance occur for corrective actions. Then depending

on the frequency of failure and other circumstances, they will take appropriate actions. The CMS policy for surveyors regarding PT monitoring and unsuccessful performance is also on the Web site noted. By reading and understanding how the CMS protocol works, laboratories can potentially diminish or prevent cease-testing orders.

On a more positive note, the laboratory industry should be extremely proud of its overall improved PT performance over the years since CLIA was first implemented. Not only do surveyors and accreditors monitor PT performance, but CMS evaluates the data in aggregate over time. In the early years, our data indicate that approximately 69 percent of all laboratories enrolled and performed successfully in PT. More recent data reflect performance that has actually topped out at up to *95 percent of laboratories enrolled and performing successfully*. This clearly demonstrates continually improved performance and the educational benefit of PT testing.

We do recognize, however, that statistically, all laboratories, even the very best, will encounter a PT failure at some point. These aberrations are accounted for in the regulations to prevent overly punitive actions against an exceptionally performing laboratory. In these instances, CMS and the regulations provide an option to allow the laboratory to undertake training and technical assistance in lieu of more stringent sanctions, as long as the laboratory has a good compliance history.

An added benefit of PT is that when PT samples have been graded, they may be used for continuing education, staff training and competency, surrogate quality control (QC), test method verification, and so on. But keep in mind that these samples may not be blood-based and you could experience a "matrix effect."

Where Do We Go from Here?

Because the health care environment is so drastically different since the 1992 regulations were published, clinical testing protocols have changed and PT is evolving for tests like those that identify genetic mutations, CMS has initiated a plan, in collaboration with the Centers for Disease Control and Prevention (CDC), our CLIA partner, to update these requirements. This means that we will reevaluate the requirements for laboratories, PT programs, grading criteria, and target values; develop a technically sound mechanism for analyte selection; and last, but not least, clarify standards for PT referral.

We do recognize, however, that statistically, all laboratories, even the very best, will encounter a PT failure at some point. These aberrations are accounted for in the regulations to prevent overly punitive actions against an exceptionally performing laboratory.

To accomplish this monumental feat, we will utilize the Clinical Laboratory Improvement Advisory Committee (CLIAC), our technical advisory committee, process to convene a work group of subject matter experts who represent all affected parties. These include laboratories, PT programs, accrediting organizations, exempt states, Veterans Affairs (VA), Department of Defense (DOD), Food and Drug Administration (FDA), and other government agency representatives.

CMS and CDC hope to assemble this distinguished work group in early 2010 to begin their extensive deliberations. It is our sincere desire that by utilizing the expertise of these individuals in the initial phase of the regulation development process, we can avoid controversy over the revised standards in the future following publication. However, the regulatory process still requires a proposed rule that solicits public comments prior to any final standards being published and implemented. So stay tuned for further CMS updates on this project.

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Patients' Genetic Information, *from page 1*

by covered health plans for eligibility determinations; premium computations; applications of any pre-existing condition exclusions; and any other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

"In combination with the new penalties for violations of the HIPAA Privacy Rule, as provided for by the American Recovery and Reinvestment Act of 2009, a use or disclosure of genetic information in violation of the HIPAA Privacy Rule could result in a fine of $100 to $50,000 or more for each violation," HHS said in a statement.

Request for Comment

The agencies included a request for comments on the interim final and temporary rules, which are effective for both group markets and individual markets 60 days after publication in the *Federal Register*.

Title I of GINA amended the Employee Retirement Income Security Act (ERISA), the Public Health Service Act, the Internal Revenue Code, and the Social Security Act to prohibit discrimination in health coverage based on genetic information. GINA builds on existing protections added by Titles I and IV of HIPAA.

The Internal Revenue Service (IRS) simultaneously released proposed rules that cross-reference the temporary rules. The agency said the text of the temporary rules serves as the text for the proposed rules. The temporary rules add to the tax regulations to prohibit adjustments in group premium or contribution rates based on an individual's genetic information.

Regulatory Definitions

Although GINA, which became law May 21, 2008, does not mandate any specific benefits, the law does establish standards generally prohibiting health benefit plans and health insurance issuers from:

- increasing the group premium or contribution amounts based on genetic information;
- requesting or requiring an individual or family member to undergo a genetic test; and
- requesting, requiring, or purchasing genetic information prior to or in connection with enrollment or at any time for underwriting purposes.

The rules provide several definitions either directly adopting or expanding on definitions in the statute. For example, the agencies said that GINA contains a statutory definition of genetic information that differs from the definition in the HIPAA portability regulations. The interim final rules revise the existing HIPAA rules' definition of genetic information to conform to GINA's definition.

Because neither HIPAA nor GINA define "dependent," the agencies said that it is necessary to turn to the final HIPAA portability rules and to one's health plan document to determine dependent status for GINA. The HIPAA rules define "dependent" as any individual who is or may become eligible for coverage under the terms of a group health plan because of a relationship to a participant.

GINA prohibits health plans from discriminating against an individual based on the genetic information of relatives, including first-, second-, third-, and fourth-degree relatives. The interim final rules treat relatives by affinity (e.g., by marriage or adoption) the same as relatives by consanguinity (i.e., relatives who share a common biological ancestor, or blood relatives). In addition, relatives who are not full

blood relatives, such as half-siblings, are treated the same as full blood relatives. The rules also provide nonexhaustive lists of individuals who are first-, second-, third-, and fourth-degree relatives.

The agencies restated and reorganized the statutory definition of genetic information as "information about the individual's genetic tests or the genetic tests of family members, the manifestation of a disease or disorder in family members of such individual (that is, family medical history), or any request of or receipt by the individual or family members of genetic services. "Genetic information" does not include information about an individual's age or sex. The agencies also addressed the application of GINA to fetuses and embryos and said that the new definition is a change from that applied under the HIPAA rules.

The rules follow the statutory language for the definition of "genetic test" to mean an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the test detects genotypes, mutations, or chromosomal changes. However, the rules also provide a nonexhaustive list providing examples of genetic tests.

The rules add a new definition of "manifestation or manifested." The rules state that a "disease, disorder, or pathological condition is manifested when an individual has been or could reasonably be diagnosed by a health care professional with appropriate training and expertise in the field of medicine involved." The definition also states that a "disease, disorder, or pathological condition is not manifested if a diagnosis is based principally on genetic information."

Prohibition on Adjusting Group Rates

Under prior law, health plans and insurance issuers were allowed to adjust premium or contribution amounts for a group health plan or group of similarly situated individuals on the basis of genetic information. Such adjustments are no longer permitted, the agencies said. Even when a plan or issuer has lawfully obtained genetic test results or other genetic information, such as if a plan has received information before the enactment of GINA, the plan or issuer is still prohibited from using that information to discriminate.

Plans still are permitted to increase premiums or contribution rates based on the manifestation of a disease or disorder in an individual, provided the manifestation is not used as genetic information to increase the premium or contribution amounts of other group members. Plans and issuers also are permitted to include costs associated with providing benefits for covered genetic tests or genetic services within the costs of providing other benefits in determining premiums or contribution amounts.

Prohibition on Collection of Genetic Information

The interim rules describe GINA's prohibitions against plans or issuers collecting genetic information, either for underwriting purposes or prior to or in connection with enrollment. The rules clarify that the term "collect" means to "request, require, or purchase" genetic information.

The rules clarify that GINA's definition of "underwriting" extends beyond rating and pricing a group policy. The definition includes changing deductibles or other cost-sharing mechanisms, or providing discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing a health risk assessment (HRA) or participating in a wellness program.

The agencies said that of particular concern are wellness programs that include

HRAs which request information about an individual's family medical history. The agencies said that because GINA defines genetic information as including family medical history, wellness programs that provide rewards to individuals who complete HRAs that request family medical history will be in violation of the law, even if the rewards are not based on the outcome of the HRA.

Plans and issuers may collect genetic information through an HRA as long as no rewards are provided and if the request is not made prior to or in connection with enrollment, the rules state. Plans and issuers also may provide rewards for completing an HRA, but only if the HRA does not collect genetic information.

HRAs also can be problematic because questions may only implicitly request genetic information, the agencies said. For example, an HRA might include such as question as, "Have you had any laboratory tests in the last two years?"

The interim rules state that if it is reasonable to expect that health information will be received as part of the collection of information, GINA's incidental collection exception will not apply unless the collection explicitly states that genetic information should not be provided.

Plans and issuers are only prohibited from collecting genetic information for underwriting purposes or prior to or in connection with enrollment, the agencies said. If an individual seeks a plan benefit, the plan or issuer may request family medical history or other genetic information to determine whether the benefit is medically appropriate for purposes of payment. However, plans and issuers may request only the minimum amount of genetic information to determine medical appropriateness.

HHS Proposed Rules

HHS said in its rule that it is proposing to make the following five key changes to the HIPAA privacy regulations:

- explicitly provide that genetic information is health information;
- prohibit health plans from using or disclosing protected health information that is genetic information for underwriting purposes;
- revise the provisions relating to the notice of privacy practices for health plans that perform underwriting;
- make a number of conforming modifications to definitions and other provisions; and
- make technical corrections to update the definition of "health plan."

Comments on the rules are due by 90 days after the rules are published in the Federal Register. *The rules are available at www.federalregister.gov/OFRUpload/OFRData/2009-22504.PI.pdf.*

The proposed rule would apply GINA's prohibition on using and disclosing protected health information that is genetic information for underwriting to all health plans that are subject to the HIPAA privacy rule, rather than solely to the plans GINA explicitly requires be subject to the prohibition. Therefore, the proposed rules would apply to:

- group health plans, health insurance issuers, health maintenance organizations;
- Medicare supplemental policies;
- long-term care policies (excluding nursing home fixed-indemnity policies);
- employee welfare benefit plans or other arrangements that are established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers;
- high-risk pools that are mechanisms established under state law to provide health insurance coverage or comparable coverage to eligible individuals;
- certain public benefit programs, such as Medicaid, the military and veterans health programs, and the Indian Health Service program.

News-At-A-Glance

OIG Work Plan: The Department of Health and Human Services Office of Inspector General (OIG) Oct. 1 released its annual work plan—a road map for projects the agency expects to undertake in the coming year. New in the fiscal year 2010 OIG Work Plan is a separate section detailing projects that were mandated by Congress in the American Recovery and Reinvestment Act of 2009 (ARRA). Those work plan items include reviews of how states have used increased Medicaid funding under ARRA and what states are doing to mitigate improper payments in their Medicaid programs. The work plan is available online at *www.oig.hhs.gov/publications/docs/workplan/2010/Work_Plan_FY_2010.pdf*.

Kickback Settlement: Three New Jersey cardiologists recently agreed to pay a total of $960,000 to settle claims that they accepted salaries from the University of Medicine and Dentistry of New Jersey (UMDNJ) in exchange for referring patients to University Hospital for cardiac procedures, according to acting U.S. attorney for the District of New Jersey Ralph J. Marra. The Department of Justice Sept. 29 announced that UMDNJ has agreed to pay the federal government $8.3 million to resolve charges that it paid kickbacks to cardiologists in an effort to ramp up the number of heart procedures performed at the hospital. The government alleged that the physicians violated the federal anti-kickback law by accepting remuneration for referrals and caused the submission of false claims to Medicare for services performed as a result of those improper referrals.

FCA Quality of Care Cases: Look for substandard quality of care to be used as the basis for False Claims Act (FCA) allegations in increasing numbers and kinds of cases, Assistant U.S. Attorney Margaret L. Hutchinson told attendees at the American Health Lawyers Association's Fraud and Compliance Forum Oct. 6. While prior case law on quality of care was "less than a paragon of clarity," Hutchinson said, the Fraud Enforcement and Recovery Act of 2009 (FERA) makes it easier for the government to advance the theory of substandard quality of care constituting a false claim. In short, "the future looks like a lot of these cases," Hutchinson told a session titled "Quality of Care: Where We Are and Where We Are Going." Hutchinson is chief of the Civil Division in the U.S. Attorney's Office for the Eastern District of Pennsylvania.

G-2 Compliance Report (ISSN 1524-0304) is published by Washington G-2 Reports, 1 Washington Park, Suite 1300, Newark, NJ 07102-3130. Tel: 973-718-4700. Fax: 973-622-0595. Web site: www.g2reports.com.

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