G2 INTELLIGENCE

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Burgess Pledges to Ensure LDTs Are Regulated Under CLIA, Not FDA

H.R. 3207 has been referred to the House Subcommittee on Health.

Rep. Michael Burgess, M.D. (R-Texas) has pledged to continue pushing for enactment of legislation that would create an expanded notification and review process for laboratory-developed tests (LDTs) at the Centers for Medicare and Medicaid Services (CMS).

Speaking April 23 at the annual meeting of the American Clinical Laboratory Association (ACLA), Burgess said he firmly believes LDT oversight authority should fall under the Clinical Laboratory Improvement Amendments (CLIA) and should not fall under the Food and Drug Administration (FDA). Burgess introduced legislation in October 2011, the Modernizing Laboratory Test Standards for Patients Act (H.R. 3207), which would ensure that LDTs would be regulated under CLIA.

The FDA in July 2010 announced plans to regulate LDTs and is working on a final guidance that would establish review based on risk levels. FDA has long asserted that it has jurisdiction over LDTs but has

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Senate HELP Committee Approves Bill For FDA Drug, Device User Fee Programs

By voice vote, the Senate Health, Education, Labor and Pensions (HELP) Committee April 25 approved legislation that would reauthorize Food and Drug Administration (FDA) user fees for medical devices and drugs, and create new user fee programs for generic drugs and biosimilars.

The legislation also would give FDA the authority to waive user fees for certain medical devices. During negotiations on the measure, FDA officials indicated they would use that authority to waive fees on lab-developed tests if and when LDTs are regulated by the agency. Groups representing clinical laboratories would prefer to have LDTs regulated by the Centers for Medicare and Medicaid Services under the Clinical Laboratory Improvement Amendments.

HELP Committee Chairman Tom Harkin (D-Iowa) said he hopes to get the Food and Drug Administration Safety and Innovation Act to the Senate floor in May.

In a statement, Harkin and HELP Committee ranking member Michael B. Enzi (R-Wyo.) said, "At a time when Congress has been deeply divided, today's markup displayed strong bipartisan cooperation."

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exercised this jurisdiction only with respect to analyte-specific reagents, the ingredients used in LDTs, and in certain assays—in vitro diagnostic multivariate index assays—that use a proprietary algorithm to produce patient-specific results.

"The FDA already has a lot on its plate" and taking on regulation of LDTs would simply slow down its overall approval process for medical devices and tests that it already regulates, said Burgess. ACLA supports the Burgess bill, saying it "offers a modern, innovative, and flexible approach that builds on the success of CLIA."

> *"CLIA needs to be modernized, and this would allow that to happen. This bill has been structured in a way to avoid harm in innovation while the FDA approach would harm innovation."*
>
> *—Rep. Michael Burgess, M.D.*

The Burgess bill would require the secretary of Health and Human Services (HHS) to establish a single publicly accessible test registry data bank of LDTs and direct-to-consumer DNA tests, which should include information on the purpose of each test, the claimed use or uses of each test, and information regarding the analytical validity of each test. Labs would be required to notify HHS (1) before marketing such a test, (2) after any significant modification of such a test, or (3) if the evidence of clinical validity is inadequate to support one or more of the claimed uses.

The measure would also require HHS, within 90 days of receiving such notification, to determine whether the test is clinically valid and would deem the secretary to have authorized marketing of the test if no response is received within 90 days. In addition, the bill would give the secretary authority to order a laboratory or test-offering entity to cease offering or marketing a test if the information submitted in notifications does not demonstrate the clinical validity of the claimed uses and the test poses a risk of immediate harm to the public health.

H.R. 3207 would set forth requirements for (1) registration of a test-offering entity, (2) information that must be included in disseminated materials and advertising, (3) notice to the secretary if a test may have caused or contributed to a death or serious bodily injury, and (4) sanctions for violations of the law ($10,000 for each violation). It also would require the secretary to administer this program solely through the CMS.

The new notification and review process would be paid for entirely through user fees paid by clinical laboratories seeking test approval.

"CLIA needs to be modernized, and this would allow that to happen," said Burgess. "This bill has been structured in a way to avoid harm in innovation while the FDA approach would harm innovation."

ACLA supports the measure. In a letter sent to Burgess endorsing the legislation, ACLA said the bill reflects the need for government regulation to keep pace with advancements in science that will move the health care delivery system to one focused on what is best for the patient, public health, and the economy.

"In particular, we note the legislation's effectiveness in reaching these goals by strengthening the current regulatory structure and eliminating duplicative regulation; enhancing public transparency for patients, providers, and regulatory agencies; and strengthening reporting for adverse events—all without additional government expenditures," said ACLA. G2

CMS Issues Final Rule Requiring Providers To Obtain National Provider Identifier Number

All providers and suppliers who qualify for a National Provider Identifier (NPI) will be required to include the NPI on any enrollment applications to Medicare and Medicaid, as well as on any payment claims, according to a final rule issued by the Centers for Medicare and Medicaid Services (CMS) April 24.

CMS said the rule will save Medicare about $1.6 billion over 10 years.

The rule also requires physicians and other professionals who are permitted to order and certify covered items and services for Medicare beneficiaries to be enrolled in Medicare. In addition, it mandates document retention and provision requirements on providers and suppliers that order and certify items and services for Medicare beneficiaries.

CMS said the rule will give it and states the ability to link provider claims to the ordering or certifying physician or eligible professional and to check for suspicious ordering activity.

CMS may revoke a provider's enrollment in federal health care programs for up to a year for failing to meet the documentation requirements. The agency said most providers that want to enroll in Medicare and Medicaid already have an NPI.

The NPI is a 10-digit number that identifies health care providers. The National Plan and Provider Enumeration System collects identifying information on health care providers and assigns each a unique NPI. CMS published an interim final rule on the NPI requirement in May 2010.

The regulation, which is scheduled for publication in the April 27 *Federal Register*, is effective June 26.

Combating Fraud

"Thanks to the [Patient Protection and] Affordable Care Act, we are expanding our work to combat fraud," CMS Deputy Administrator for Program Integrity Peter Budetti said in a press release. "This rule will save money for taxpayers and ensure people with Medicare get high-quality care."

CMS said it based its Medicare savings estimate on a decrease in the use of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS); imaging services; clinical laboratory services; and home health care because a small number of patients will go to physicians without enrollment numbers and thus will not get referrals to these services.

Some provider claims without proper documentation, including some fraudulent claims, could be denied as a result of the rule, but the agency said it does not have "a basis for quantifying the value of such claims."

The regulation implements Section 1128J(e) of the Social Security Act, added by the Patient Protection and Affordable Care Act, which requires that all providers and suppliers eligible for an NPI include it on all applications and payment claims for federal health care programs.

The final rule may be downloaded from the *Federal Register* site at *www.federalregister.gov*.

focus on: Stark Regulations

Appeals Court Expounds on Physician Self-Referral Violations

The U.S. Court of Appeals for the Fourth Circuit March 30 overruled and sent back to a lower court a ruling that required a hospital to repay the government $44.9 million, in part for violating the Stark law banning physician self-referrals (*United States ex rel. Drakeford v. Tuomey Healthcare System Inc.*, 4th Cir., No. 10-1819).

The appeals court said the decision of the U.S. District Court for the District of South Carolina was improper because it was based on jury findings that the district court had set aside. In the qui tam lawsuit, joined by the U.S. Department of Justice, the jury found violations of the Stark law but not of the False Claims Act. Faced with this split, the court set aside the verdict and ordered a new trial.

But after a post-trial briefing by the parties, the district court ordered Tuomey Hospital to repay the $44.9 million in damages, based in part on the finding of Stark law violations. The Fourth Circuit noted that because the entire jury verdict had been set aside in favor of a new trial, there was no basis for granting the government's claim for damages.

Background of the Case

The dispute relates to payments by a hospital to physicians for outpatient procedures that they performed at the hospital.

In 2005, Tuomey Hospital in Sumter County, S.C., entered into contracts with several specialists, including physicians who were considering performing outpatient surgical procedures at their own offices rather than at the hospital. The contracts obligated the physicians to provide outpatient procedures solely at Tuomey Hospital. The physicians agreed to assign to the hospital all Medicare and Medicaid payments they received. The contracts provided for physicians to receive a base salary and additional payments based on amounts that the hospital collected for their professional services.

Though the appellate court ruled mainly on procedural grounds, the decision by a two-judge majority went further to opine on the Stark issues raised by the case. The third judge thought it premature to do so until the jury and district court had ruled on them.

Perspectives on the Case

In comments to *NIR*, attorney Robert E. Mazer, a principal at Ober/Kaler (Baltimore), said the majority's decision is significant because of the particular government interpretations of the Stark law and regulations that it upheld and because it indicates that courts will likely give significant weight to agency interpretations presented in the preamble to the Stark regulations.

"Generally, when independent physicians (that is, physicians who do not work for a hospital or a related entity) perform procedures in a hospital facility, the physician or his medical group bills the patient or payer for his or her professional services.

The hospital bills for use of its facility (the facility fee), including related supplies, equipment, and nonphysician personnel," Mazer noted.

"In this case, a contract between the parties required the physicians to perform certain outpatient surgical procedures at the hospital and for the hospital to bill for both the physician's professional service and the facility fee. The hospital would pay the physician for his or her professional services. The payment formula is somewhat unclear, but it appears that the physician's compensation reflected a fixed salary and amounts collected for his or her professional services. It also appears that the physician may have received more than the payment received by the hospital for his or her professional services."

The Stark Physician Self-Referral Law

- Prohibits a physician (or an immediate family member) from making Medicare and Medicaid referrals for designated health services (which include outpatient hospital services) to an entity with which the physician (or immediate family member) has a financial arrangement, either by ownership interest or compensation arrangements or both.
- Bars billing anyone pursuant to a prohibited self-referral.

There are numerous exceptions in the statute and related regulations issued by the Centers for Medicare and Medicaid Services.

The court majority addressed two Stark issues, Mazer pointed out. "First, whether the physician made a 'referral' to the hospital for the facility fee when he or she performed an outpatient procedure at the hospital. The issue could have been stated more precisely as whether there was a referral for outpatient hospital services, which is a designated health service under the Stark statute. The Stark regulation's definition of referral excludes a service personally performed by the referring physician. The court majority, however, did not extend this to the related hospital service for which the hospital received a facility fee. In reaching this conclusion, the majority relied on statements from the preamble to the Stark II rulemaking. The majority stated that Supreme Court precedent required it to defer to those interpretations, even if the court would have otherwise interpreted the statute differently.

"Second, the court addressed whether there was an indirect compensation arrangement between the physician and the hospital," Mazer said. "One of the requirements for such an arrangement is that the physician's payment varies with or takes into account the volume or value of his or her referrals or other business that he or she generated for the health care provider.

"It appears that, technically, payments to the physician did not fluctuate with his or her referrals to the hospital. This is because under Stark regulations a service personally performed by a physician is not considered to have resulted from a referral, and the physician's payment from the hospital fluctuated based only on what the hospital collected for his or her professional services.

"Again, relying on preamble language, the court majority accepted the government's position that payments take referrals into account if the physician's payment reflected the facility fees that the hospital received as a result of his or her referrals."

The decision indicates that even a fixed payment—a payment that doesn't change based on actual referrals—may impermissibly reflect the volume or value of referrals resulting in an indirect compensation arrangement, Mazer concluded. "While the particular language may differ, several exceptions to the Stark law require that payments be unrelated to the volume or value of referrals. This concept is also incorporated in various safe harbors under the federal anti-kickback statute. Therefore, the majority's decision could have potentially wide impact." G2

Senate HELP Committee Approves Bill, *from p. 1*

They noted that the legislation builds upon the current user fee programs for devices and brand-name drugs, which will expire Sept. 30.

If new drug and medical device user fee agreements are not authorized before the current ones expires, FDA must lay off nearly 2,000 employees, the senators said. The fees supplement congressional appropriations for the agency.

The bill would allow FDA to collect prescription drug user fees from industry from fiscal year 2013 through FY 2017, according to a summary of the bill. For FY 2013, it would set total prescription drug user fee revenue at $693 million.

Additionally, the bill would allow FDA to collect $595 million in medical device user fees over the five-year period of FY 2013 to FY 2017, the summary said. FDA also would be able to collect generic drug user fees of $299 million each year from FY 2012 through FY 2017. Biosimilar user fees would be based on inflation-adjusted prescription drug user fee amounts for each fiscal year.

The House Energy and Commerce Committee, which had originally scheduled an April 26 markup of the user fees legislation, has postponed consideration until May 8. In anticipation of the House markup, Energy and Commerce Committee Republicans released a memo on their version of the user fees bill; they said the bill also would make changes to the agency's guidance document process and advisory panel conflict-of-interest policy.

In anticipation of the markup, the Advanced Medical Technology Association said in an April 23 letter to House and Senate committee leaders that the user fee agreement reached recently between FDA and industry, which is reflected in the legislation, "is a good one for patients, industry and the agency."

Medicare's Hospital Trust Fund Solvent Until 2024, Report Says

Medicare's Part A Hospital Insurance Trust Fund will be solvent until 2024, the same as estimated last year, the program's trustees said April 23 in their annual report on the financial state of Medicare.

The trustees said the trust fund would have gone bankrupt in 2016 without the Medicare provisions in the Patient Protection and Affordable Care Act. Many of those provisions have yet to be implemented. The law reduced projected Medicare spending more than $500 billion over 10 years.

The 285-page report, the *2012 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*, said hospital trust fund expenditures have exceeded income annually since 2008 and are projected to continue to do so.

The trustees—who include Health and Human Services Secretary Kathleen Sebelius and Treasury Secretary Timothy F. Geithner—said that although Medicare will remain financially viable until 2024, further reforms beyond those included in PPACA will be needed to ensure the program's long-term solvency.

"The financial projections in this report indicate a need for additional steps to address

Medicare's remaining financial challenges," Geithner told reporters at a briefing. "Consideration of further reforms should occur in the near future. The sooner solutions are enacted, the more flexible and gradual they can be. Moreover, the early introduction of reforms increases the time available for affected individuals and organizations—including health care providers, beneficiaries, and taxpayers—to adjust their expectations."

Sebelius told reporters that Medicare policy in PPACA could do even more to sustain Medicare in the future than outlined in the trustees report, but she said more needs to be done to reform the program. She said President Obama's budget plan released in February would further help Medicare by reducing fraud and abuse, ending unnecessary payments, and helping providers efficiently deliver care.

The report said Medicare spent $549 billion in 2011, and under current law the trustees project program spending will increase at a somewhat faster pace than either aggregate workers' earnings or the economy overall.

Future Cost Growth

Medicare's future cost growth will primarily be due to growth in the number of beneficiaries and partly due to an increase in expenditures per beneficiary, which are projected to rise slightly faster than the per capita rate of growth of the economy overall, the report said.

Based on the intermediate set of assumptions and current law, Medicare expenditures as a percentage of the gross domestic product (GDP) would increase from the current 3.7 percent to a projected 6.7 percent by 2086, it said.

For 2012, the trustees said they expect total Medicare expenditures to exceed revenue by a significant margin due to recent decreases in Medicare payroll tax income caused by the weak economy.

Part B costs are expected to double as a share of GDP over the next 75 years, from 2 percent to 4 percent, a projection that assumes a reduction of 31 percent in payment rates for physician services in 2013, as required under current law, the report said. If lawmakers cancel this cut, which they likely will, Part B costs "will significantly exceed the projections" estimated by the trustees, the report said.

Part A expenditure growth is expected to average 5.3 percent per year over the next 10 years, the report said. Although the hospital trust fund is expected to be insolvent by 2024, funding for Part B is adequate because premiums and general revenue for Part B are reset each year to match expected costs, the report said.

The trustees said that projections of Medicare costs are "highly uncertain, especially when looking out more than several decades."

"One reason for uncertainty is that scientific advances will make possible new interventions, procedures, and therapies. Some conditions that are untreatable today will be handled routinely in the future," the report said. "While most technological advances to date have tended to increase costs, the health care landscape is shifting. No one knows whether these future developments will, on balance, increase or decrease costs."

The report is available at *www.cms.gov/ReportsTrustFunds/downloads/tr2012.pdf.*

LDT Guidance Likely Delayed Until After Election

Final guidance on lab-developed tests being developed by the Food and Drug Administration (FDA) is likely to be delayed until after the fall elections, predicts a former FDA official. Scott Gottlieb, M.D., resident fellow at the American Enterprise Institute and deputy commissioner of the FDA from 2005 to 2007, said that while in vitro diagnostic test manufacturers are pushing FDA to get the guidance out, there is not a great deal of urgency because "there's not a lot of data that there have been problems in this space." Gottlieb gave his prediction April 23 during the annual meeting of the American Clinical Laboratory Association.

The FDA in 2010 proposed to regulate LDTs under what it considered its "enforcement discretion." The agency is currently working on guidance that will set up a regulatory framework for LDTs based on risk with exceptions for rare diseases, emerging biothreats, and emerging infectious diseases. The lab industry, however, is pushing for LDTs to be regulated by the Centers for Medicare and Medicaid Services under the Clinical Laboratory Improvement Amendments (CLIA). Legislation introduced by Rep. Michael Burgess (R-Texas) would set up a system within CLIA for LDT oversight (*see related story on page 1*).

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