G2 Compliance Report

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For Hospitals, Laboratories and Physician Practices

Kimberly Scott, Managing Editor, kscott@G2Intelligence.com Issue 11-11 • Nov.-Dec. 2011

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LabCorp, Quest Settlements Spawn Another Lawsuit

Recent settlements by the country's two largest clinical laboratory companies over allegations of illegal price discounts have spawned yet another lawsuit involving charges of overbilling.

In a complaint unsealed in federal court Sept. 9, NPT Associates and Andrew Baker, its principal partner, charge that LabCorp (Burlington, N.C.) entered into a sham contract with United Healthcare Group (UHG) as part of a scheme that was essentially a kickback and led to LabCorp's violating the False Claims Act *(United States ex rel. NPT Associates v. Laboratory Corporation of America Holdings*). Baker is former chief executive officer of Unilab.

The complaint, unsealed by the U.S. District Court for the Southern District of New York, charged that LabCorp entered into a contract with a UHG affiliate in 2006 solely to obtain the Medicare business of the insurance company's in-network physicians, which violates the anti-kickback statute.

The complaint also alleges that LabCorp violated the False Claims Act by falsely certifying it had complied with all laws and regulations that are a precondition of Medicare payment, including the anti-kickback

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Obama Deficit-Reduction Plan Would Save $6.4 Billion by Cutting Health Care Fraud

President Obama Sept. 19 proposed reducing Medicare spending $248 billion over 10 years and Medicaid spending $72 billion as part of a $3.2 trillion deficit-reduction package that also seeks to strengthen health care anti-fraud and abuse activities. The Medicaid and Medicare anti-fraud proposals would save $6.4 billion over 10 years.

The plan—which did not include raising Medicare's eligibility age—would affect the payments of a wide variety of health care providers, including drug companies, hospitals, nursing homes, and home health agencies. The plan also would strengthen health care fraud and abuse activities and increase costs for new beneficiaries by imposing higher Part B deductibles and introducing cost sharing for home health services.

In a White House speech, the president said he would veto any deficit-reduction plan produced by Congress that included Medicare cuts but not tax increases on wealthy Americans and corporations. The proposal

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LabCorp, Quest Settlements Spawn Another Lawsuit, *from page 1*

statute. As part of their pleadings, the relators alleged instances where LabCorp's officials implied that the contract with UHG was essentially a kickback to increase the laboratory's Medicare business. In one example, LabCorp Chief Operating Officer Donald Hardison allegedly said that if LabCorp did not obtain the Medicare business through the UHG contract, it would "lose its shirt."

Baker also is involved in a lawsuit against Quest Diagnostics. In a case filed in 2005, Baker and several other former employees of Unilab accused Quest and Unilab of engaging in a so-called "pull-through" scheme whereby they charged customers below-cost rates in exchange for referrals of Medicare and Medicaid reimbursable lab tests. Baker has estimated that Quest's alleged abuses cost the federal government more than $1 billion in inflated lab bills from 1996 through 2005 and hundreds of millions more in the six years since.

Baker brought the case under the federal False Claims Act and requested that the government intervene in the case, but officials with the Department of Justice in July of this year declined. Quest has vehemently denied the allegations, saying it does not provide kickbacks to doctors, insurers, or anyone else to induce referrals of any testing.

Quest Diagnostics earlier this year agreed to a $241 million settlement with the state of California over charges that the company did not comply with the state's "comparable charge" regulations, resulting in overpayment by California's Medicaid program. LabCorp agreed to pay $49.5 million over similar allegations. G2

Court Denies Rehearing on Myriad Gene Patent Case

The U.S. Court of Appeals for the Federal Circuit has turned down petitions by both sides to again air arguments in the legal challenge to gene patents held by Myriad Genetics (Salt Lake City).

The rehearing request by Myriad and the American Civil Liberties Union (ACLU) related to a July 29 court ruling that upheld patents granted to Myriad Genetics and the University of Utah Research Foundation for the BRCA1 and BRCA2 genes associated with hereditary breast and ovarian cancer (*GCR, Sept. 2011, p. 4*). That decision overturned a lower court's ruling that the gene patents were invalid because the genes are products of nature.

The plaintiffs' request for a panel rehearing, filed by the ACLU, alleged factual and legal errors in the decision on standing and patient-eligibility issues, primarily in its interpretation of "isolated DNA." The appellate court ruled that Myriad's patents are valid because they involve DNA isolates that are "markedly different" in molecular composition than the DNA that exists in chromosomes in the body.

Myriad's petition for a rehearing sought to make the entire matter moot on the issue of whether any of the plaintiffs in the case had the standing needed to continue.

The petition from ACLU was denied on Sept. 13, that from Myriad on Sept. 16. Each side has 90 days from the denial date to petition the Supreme Court. The plaintiffs plan to file such a petition with the high court, according to the ACLU. This could be a long shot, court watchers say, since the court's calendar is quite limited; however, the court has shown an interest in patent cases in recent months and could opt to take on the challenge to Myriad.

The biotech firm hailed its victory before the appellate court, saying the DNA iso-

lates in dispute are "new chemical matter with important clinical utilities which can exist only as a product of human ingenuity."

The appellate decision also benefits the biotechnology, agricultural, and pharmaceuticals industries that rely on strong patent protection to develop products to better people's lives. Nearly 20 percent of human genes are patented, including genes associated with Alzheimer's disease, muscular dystrophy, colon cancer, asthma, and many other illnesses.

But the broad coalition of providers, researchers, and patients that filed suit against Myriad say the breast and cancer gene patents give the company a monopoly on the testing, stifling research and curtailing women's access to a lifesaving test. As the patent holder, Myriad has the exclusive right to perform testing on the BRCA genes, license the testing to other users, and threaten litigation against any unlicensed use. G2

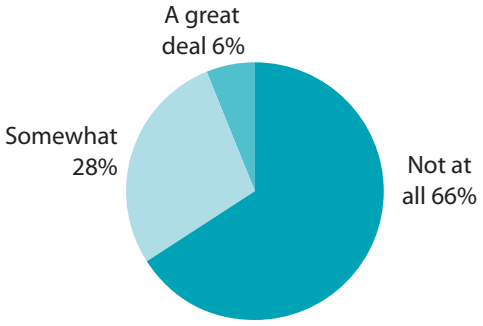
No Increase in Whistleblowers From Dodd-Frank, But Communication Has Improved

Implementation of the Dodd-Frank Act in 2010, which many predicted would lead to a spike in the number of claims brought by whistleblowers, has not had the expected effect, according to a new survey from the Society of Corporate Compliance and Ethics (SCCE) and the Health Care Compliance Association (HCCA).

The measure, signed into law in July 2010, implements financial regulatory reform and has been touted as the most sweeping change to financial regulation in the United States since the Great Depression.

Perhaps no area gained more headlines than the act's provision for whistleblowers to receive between 10 percent and 30 percent of any potential fines over $1 million collected by the U.S. government.

To what degree has your organization modified its compliance program as a result of Dodd-Frank?



Source: SCCE-HCCA survey on Dodd-Frank

"Some foresaw this provision triggering a firestorm of both legitimate and mal-intended claims," notes the survey report. "During the [Securities and Exchange Commission's] rule-making process there were also fears expressed that it would undermine existing compliance and ethics programs by encouraging employees to avoid internal mechanisms for reporting wrongdoing and take allegations straight to the SEC."

A leading business group, in its comment letter to the SEC, wrote that the whistleblower provisions "may undermine the functioning of effective corporate compliance programs by relegating them to the sidelines in the process of identifying and remedying violations of securities laws."

The SCCE and the HCCA jointly fielded a survey to determine the impact, if any, Dodd-Frank has had on compliance and ethics programs. The goal was to determine

if the added incentives for employees to take their claims outside of the company was affecting the structure of compliance programs.

The survey revealed that relatively little has changed as a result of Dodd-Frank. While companies are increasing communications to employees, the act's whistleblower provisions have not led to wholesale changes to compliance programs. "Instead, they have primarily led to what most would likely welcome: increased communication to employees about what to do when encountering wrongdoing and greater training of managers about how to handle reported wrongdoing," said the report.

"While companies are increasing communications to employees, the act's whistleblower provisions have not led to wholesale changes to compliance programs."

Just 6 percent of respondents reported that Dodd-Frank had led to a "great deal" of change to their compliance program. To be sure, there were variations by industry type and company structure. For example, while only 5 percent of health care companies reported their program had changed a great deal, 11 percent of non-health care companies reported this level of change.

One possible explanation for the relative lack of change was that anonymous help lines were already fairly ubiquitous. Overall, 90 percent of respondents reported that their employer already had an anonymous helpline in place. Among publicly traded companies, 99 percent reported a helpline already present.

However, some changes were made as a result of Dodd-Frank, according to the survey. Anti-retaliation policies were reported changed by 13 percent of respondents. Increased communications to employees about opportunities to report wrongdoing were reported by 75 percent, and increased communications to managers about how to handle employee allegations of wrongdoing were reported by 46 percent.

The full report, "Dodd-Frank: Big Headlines, Not-So-Big Impact," is available online at *www.hcca-info.org* or *www.corporate compliance.org*.

HHS OIG to Examine Lab Trends and Payments in 2012

The Department of Health and Human Services Office of Inspector General (OIG) will examine payment for glycated hemoglobin A1C tests, trends in laboratory utilization, and how payments for lab tests compare under Medicare, Medicaid, and the Federal Employee Health Benefits (FEHB) Program, the agency says in its 2012 work plan, released in early October.

The OIG will review Medicare contractors' procedures for screening the frequency of clinical laboratory claims for glycated hemoglobin A1C tests and determine the appropriateness of Medicare payments for these tests. Preliminary OIG work at two Medicare contractors showed variations in the procedures for screening the frequency of these tests, says the OIG, noting that it is not considered reasonable and necessary to perform the test more often than once every three months on a controlled diabetic patient unless documentation supports the medical necessity of testing in excess of national coverage determination guidelines.

The agency also says it will review trends in laboratory utilization under Medicare and will determine how the methods for establishing Medicare laboratory test payment rates vary from state Medicaid and the FEHB Program.

The entire work plan is available online at *www.oig.hhs.gov.*

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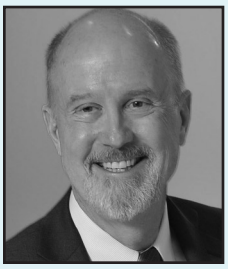
COMPLIANCE PERSPECTIVES

Changes to HIPAA Privacy Rule and CLIA Regs Will Require Labs to Release Test Results to Patients

Joshua Freemire, Esq., is an associate in the Baltimore office of Ober|Kaler



James Wieland, Esq., is a principal in the Baltimore office of Ober|Kaler

If the most recent proposed changes to the Health Insurance Portability and Accountability Act (HIPAA) privacy rule and Clinical Laboratory Improvement Amendments (CLIA) regulations are finalized as proposed, laboratories across America will be obligated to provide test results to individual patients upon request. The changes to CLIA and the HIPAA privacy rule are coordinated and, taken together, would result in a marked change from the current web of state-specific laboratory laws (which often prohibits providing patients their own test results) and will require many laboratories to develop HIPAA-compliant policies and procedures for accepting, processing, and responding to patient requests for protected health information. For laboratories, a patient request for health information maintained by the laboratory would include a copy of the requesting patient's laboratory reports.

The Privacy Rule's Right-of-Access Provisions

HIPAA has, since its inception, given patients a right to request a copy of their protected health information, if contained in a "designated record set," subject to certain exceptions. These exceptions included one that exempted covered entities subject to CLIA. Laboratories, in other words, were not required to comply with the privacy rule's right-of-access provisions, which also include a deadline for the covered entity's response and patient appeal rights where a request for access is denied. The Health Information Technology for Economic and Clinical Health (HITECH) Act added statutory provisions extending this right of access to records maintained in electronic form and providing patients a right to request that the covered entity transmit a copy of the requested records to an entity or person designated by the individual (such as, for example, the individual's personal health records provider). Unfortunately, the regulations implementing the HITECH Act's changes have not yet been finalized, leaving the privacy rule's right-of-access provisions uncertain.

If finalized, the proposal will eliminate the privacy rule's exception for CLIA-covered or exempt entities. Laboratories, in terms of the privacy rule's right of access, will now need to comply with patient requests for information in the same manner as other covered entities. Because of the timing of the proposed rule relative to the regulatory revisions required by the HITECH Act, however, laboratories may face challenges drafting policies and crafting procedures to comply with the full extent of the privacy rule.

Changes to HIPAA and CLIA

The rulemaking proposes changes to both the privacy rule and the CLIA regulations. As the notice explains, the proposed changes will provide "individuals the right to receive their test reports directly from laboratories by removing the exceptions for CLIA-certified laboratories and CLIA-exempt laboratories from the [privacy rule] provision that provides individuals with the right of access to their protected health information." Under the changes to CLIA, laboratories will be *permitted* to provide patient test results and under the changes to the privacy rule, they will no longer be exempted from the privacy rule's *requirement* that they do so.

The relevant CLIA regulations are found at 42 C.F.R. §493.1291. Under the existing rule, laboratories may only release test results to an "authorized person" and, if applicable, the individuals responsible for using the test results (including their representatives or the laboratory that originally requested the test). Into that section, the rulemaking proposes adding an additional group who may receive test results:

> Upon a patient's request, the laboratory may provide access to completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient.

Notably, laboratories *may* release test results to patients, and then only when they *may* be authenticated. The rulemaking explains that the may is somewhat illusory—as laboratories are usually "covered entities"[1] under the privacy rule, they would be *required* to comply with the privacy rule provisions granting patients a right of access. These rules, however, apply only where the covered entity can be certain that the person requesting access is indeed the patient whose records are sought (or someone similarly authorized, such as a personal representative). As the rulemaking notes, this authentication is especially important in a laboratory context where anonymous testing is not unusual. If the laboratory cannot be certain, for instance, that the patient requesting the results of accession No. 123456, is in fact "Anonymous – ID No. 67890" who was the subject of that accession, it is not obligated to release the results.

The affected privacy rule provision is found at 42 C.F.R §164.524. As that regulation currently reads, covered entities that are "Subject to the Clinical Laboratory Improvements Amendments of 1988, 42 U.S.C. 263a" and CLIA-exempt entities are exempted from the right-of-access requirement. Under the proposed rule, these sections would simply be deleted from the regulation. As a result, the proposal explains:

> HIPAA covered entities that are subject to CLIA would have the same obligations as other types of covered health care providers with respect to providing individuals with access to their protected health information in accordance with §164.524. Similarly, HIPAA covered entities that are CLIA-exempt laboratories (as the term is defined at 42 CFR 493.2) would no longer be excepted from HIPAA's right of access under §164.524(a)(1)(iii)(B). As with other covered entities, HIPAA covered laboratories would be required to provide access to the individual or the individual's personal representative.

Covered entity laboratories would also be required to have in place compliant policies and procedures, including policies and procedures governing the receipt, processing, and response to requests within HIPAA-compliant time limits.

Changes to State Laws

Importantly, the proposed rule acknowledges that state law frequently prohibits laboratories from providing test results directly to patients.[2] Other states permit disclosure only with the permission of the ordering physician.[3] In these states, the

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[1] *Relevant to laboratories, HIPAA and its implementing regulations define a "covered entity" to include a health care provider that conducts (or has conducted at least one) electronic transactions, including, among others, submitting health care claims or similar encounter information (for payment purposes), coordination of benefits activities, checking health care claim status, and certifying referrals or authorizations. Most laboratories perform all or at least some of these activities electronically, but smaller laboratories that do not should investigate whether they are, in fact, "covered entities."*

[2] *The proposed rule provides a chart identifying Arkansas, Georgia, Hawaii, Illinois, Kansas, Maine, Missouri, Pennsylvania, Rhode Island, Tennessee, Washington, Wisconsin, and Wyoming as states where such laws are in effect.*

[3] *The proposed rule provides a chart identifying California, Connecticut, Florida, Massachusetts, Michigan, New York, and Virginia as states where such laws are in effect.*

proposal will effectuate a direct change in the law. HIPAA's preemption provisions require the application of the HIPAA privacy rule where HIPAA is more stringent and complying with both the privacy rule and state laws is impossible.

In the case of state laws restricting or prohibiting patients' access to their own test results, compliance with both provisions is certainly impossible, and, further, the state laws at issue stand as an obstacle to accomplishing the purposes of HIPAA. Thus, in states that prohibit patient access, state laws would be preempted by the revised privacy rule provisions. In states where, heretofore, no patient access law had existed, the proposed rule, if final, would become the applicable legal standard. In terms of patient access, the proposed rule makes clear that *all* relevant state laws will be preempted unless they provide individuals a "more expansive" right of access.

Burden Calculations, Effective Dates

The proposed rule specifically solicits comments regarding the effect complying with the new access requirements could have on laboratories. Included in the proposal are detailed calculations of the potential costs imposed (including employee time to create and implement compliant policies and procedures and to receive, record, and respond to patient requests) but uncertainty in the assumptions underlying the calculations resulted in a wide range of potential financial impacts: estimated costs through 2011 range from $3 million to $26 million for all impacted laboratories. Obviously, laboratories in states where providing test results to patients is currently illegal will bear the disproportionate portion of this burden as each must create a compliant response program "from scratch."

This currently is just a proposal—the publication of a final rule, addressing and responding to comments where appropriate, is necessary before any of the proposed changes take effect. A final rule, when published, would take effect 60 days from the date of publication. In accordance with the proposed changes to 45 CFR §160.105[4] (which themselves have not been finalized), laboratories would be required to comply with the provisions of the final rule within 180 days of the rule's effective date. Clinical laboratories would therefore have a total of 240 days from publication of the final rule to comply.

Current Unsettled State of the Privacy Rule

The rulemaking's proposed changes to the privacy rule and CLIA regulations obligate laboratories to comply with the privacy rule. Fair enough. The privacy rule itself, however, is itself in flux. The rulemaking, in other words, proposes obligating laboratories to craft policies and procedures to comply with the currently existing privacy rule now and then modify them soon thereafter when the changes mandated by the HITECH Act are finalized.

Responding to requirements and changes in the HITECH Act, passed as part of 2009's American Recovery and Reinvestment Act, the Centers for Medicare and Medicaid Services (CMS) issued a proposed rule substantially altering the privacy rule in July 2010. Among the changes made, provisions of the proposed rule required that covered entities provide individuals with access to their health information in electronic form in a machine-readable format of the individual's choosing (where it is readily producible in such a format). Changes were also proposed to the way that covered entities are permitted to charge individuals for producing

[4] *The changes provide that changes to the privacy and security rules (or any other regulatory changes affecting HIPAA requirements) must be made effective at least 180 days from the effective date of the final rule making the changes. This change itself was proposed as part of the regulations issued to implement much of the HITECH Act's requirements.*

such material, including permitting charges for the time spent formatting or creating the information and cost-based fees for portable media (where, for example, an individual requests the information be provided on a DVD).

Currently, the privacy rule provides for neither of these requirements. Covered entities are required to produce health information in a form or format requested by the individual, but it is not clear that they are required to provide information in an electronic format. Similarly, entities are specifically prohibited from charging patients for time spent "searching for or retrieving" information and may charge requesting patients only a "reasonable, cost-based" fee based on the cost of copying the (presumably paper) information and postage fees (where applicable).

The proposed rule was published Sept. 14, 2011, in the* Federal Register. *To be considered, comments must be filed by 5 p.m. on Nov. 14, 2011. The proposal specifically requests comments on several areas, including, especially, the burdens created by this new requirement for laboratories.

Assuming for the moment, as the proposed rule itself does, that the proposal will be finalized and made effective before the proposed changes to the privacy rule are made effective, laboratories will be asked to craft two sets of policies, not one. Initially, and within the 240-day compliance period, they will be required to create policies, train staff, and implement policies and procedures that comply with the currently effective provisions of the privacy rule. Shortly thereafter, they will be required to revise those policies (and presumably retrain responsible staff members) and implement new policies conforming with the provisions of the final rule implementing the changes required by the HITECH Act.

Ober|Kaler's Comments

The proposed changes to CLIA and the privacy rule seem minor but will require substantial work on the part of many laboratories, especially those in states where the provision of test results to patients was previously not permitted. For laboratories in these states, the work to prepare effective policies and procedures, train staff, and implement processes to receive and compliantly respond to patient communications will likely take time—perhaps more than the 240 days promised by the proposed rule. Similarly, the burdens of compliance will fall disproportionately on laboratories in these states. To the extent that laboratories or other interested parties believe that the compliance period provided by CMS is insufficient or that the burden calculations in the proposed rule understate the work required, commenting on the proposal offers an opportunity to positively impact the final rule's contents.

Similarly, laboratories and other affected entities everywhere should be concerned that the rule proposes to obligate them to comply with a standard that itself is not finalized. It is not clear from the rulemaking why the proposed changes to CLIA and the privacy rule are of such a time-sensitive nature that they will require finalization before the HITECH-mandated adjustments to the privacy rule are finalized. While progression toward universality in electronic health records and health information exchange communications promises substantial financial and patient care benefits, it is also essential that such progress be made in an orderly fashion that does not unnecessarily place the cost of compliance (or double compliance!) on providers.

Joshua Freemire and James Wieland can be reached at Ober|Kaler, 100 Light St., Baltimore, Md. 21202. Phone: 410-685-1120. E-mail: jjfreemire@ober.com and jbwieland@ober.com.

Obama Deficit-Reduction Plan, *from page 1*

was submitted to the congressional Joint Select Committee on Deficit Reduction, which is tasked with reaching agreement on a $1.5 trillion deficit-reduction plan this fall.

The White House said 90 percent of the Medicare savings, or $224 billion, would come from reducing overpayments. Savings affecting beneficiaries do not begin until 2017, it added.

Medicare Fraud Proposals

To save about $5 billion over the next 10 years, the administration offered the following Medicare anti-fraud proposals:

- Recover erroneous payments made to insurers participating in Medicare Advantage. This proposal would require CMS to extrapolate the error rate found in risk adjustment validation audits to the entire Medicare Advantage contract payment for a given year, leading to recoupment of overpayments made to these plans. This proposal will save approximately $2.3 billion over 10 years.

- Dedicate penalties for failure to use electronic health records toward deficit reduction beginning in 2021. Currently the penalty (which will start in 2015) is to be credited to a special account beginning in 2020. This will save approximately $500 million over 10 years.

- Update Medicare payments to more appropriately account for utilization of advanced imaging. Beginning in 2013, this proposal implements a payment adjustment for advanced imaging equipment to account for higher levels of utilization of certain types of equipment. This proposal will save approximately $400 million over 10 years.

- Require prior authorization for advanced imaging, beginning in 2013. This proposal will save approximately $900 million over 10 years.

Some have criticized the White House for saying the proposals on imaging are fraud-related. Essentially, the proposals pick up recommendations made by MedPAC for adjusting imaging reimbursement by changing equipment utilization assumptions and for requiring preauthorization for some advanced imaging services, most likely advanced imaging in the in-office setting.

Medicaid Fraud Proposals

To save $1.4 billion over the next 10 years, the administration proposed the following Medicaid anti-fraud recommendations:

- Strengthen third-party liability for Medicaid beneficiary claims;

- Require manufacturers that improperly report items for Medicaid drug coverage to fully repay states;

- Track high prescribers and utilizers of prescription drugs in Medicaid;

- Enforce Medicaid drug rebate agreements;

- Increase penalties on drug manufacturers for fraudulent noncompliance with Medicaid drug rebate agreements;

- Require drugs to be properly listed with the Food and Drug Administration to receive Medicaid coverage; and
- Prohibit states from using federal funds as the state share of Medicaid or Children's Health Insurance Program, unless specifically authorized by law.

Super Committee Asked to Target Health Care Fraud

Two senators have asked the congressional committee charged with reducing the federal budget deficit to target health care fraud in their deliberations, but attorneys say additional savings from such initiatives might be difficult to find.

Sens. Thomas R. Carper (D-Del.) and Tom Coburn (R-Okla.) Sept. 29 sent a letter to the Joint Select Committee on Deficit Reduction asking the panel to consider legislation (S. 1251) they have introduced that would give the federal government new anti-fraud tools.

Several panel members have said increased anti-fraud efforts could yield significant savings to help cut the deficit, and beneficiary advocacy groups have urged the committee to target health care fraud to avoid cutting Medicare and Medicaid benefits to the poor and elderly.

While welcoming the focus on reducing health care fraud, Richard P. Kusserow, a defense attorney in the field and former inspector general for the Department of Health and Human Services, said the federal government was given considerable resources in the health care reform law to fight fraud, and additional funding might not yield significant savings. Kusserow is chief executive officer of Strategic Management, Alexandria, Va. He served as HHS IG from 1981 to 1992.

"No one wants to have fraud and abuse, but you don't [get rid of it] with a stroke of the pen," he said. Kusserow said fraud and abuse in federal health programs is like a "hydra's head"—as soon as one scheme is stopped, perpetrators find another way to defraud the system. "Every time you cut off one of the avenues, you get two others," he said.

Kusserow said it is "commendable" that lawmakers want to increase anti-fraud efforts. But he added it is unlikely that significantly more savings will be realized than those targeted in the health care reform law.

The Patient Protection and Affordable Care Act contains $350 million in new funding over the next 10 years to coordinate federal and state anti-fraud efforts. HHS Secretary Kathleen Sebelius has said the law is "the strongest health care fraud legislation in our history."

Reducing health care fraud and abuse has emerged as a possible method by which the congressional panel, known as the super committee, could help reduce the federal budget deficit. At the committee's first public hearing Sept. 13, several panel members said savings generated from curtailing Medicare and Medicaid fraud and abuse could yield a significant amount of money to put toward deficit reduction.

In his appearance before the panel, Congressional Budget Office Director Douglas W. Elmendorf pledged to work with lawmakers in examining fraud and abuse policy. He cautioned lawmakers, however, that there was "no evidence" that adopting additional policies to curb fraud and abuse could provide substantial savings to put toward a committee package.

The 12-member panel, which is bipartisan and bicameral, was created by the Budget Control Act of 2011. The committee will consider budget cuts and revenue increases in its attempt to reach its deficit-reduction target of $1.5 trillion over 10 years.

Failure to recommend a legislative package would trigger across-the-board spending cuts, such as a 2 percent reduction for Medicare, but no automatic cuts to Medicaid. Under the law, the panel is to report its ideas, with legislative language, no later than Nov. 23 and send it to the floor of the House and Senate for passage before Dec. 23.

Sen. Jon Kyl (R-Ariz.) said "a very substantial amount of administrative savings" could be made available by reducing fraud and abuse in Medicare, Medicaid, and Social Security, which he said totaled $125 billion in 2010.

Elmendorf cautioned that the amount of improper payments tracked by the federal government cannot all be linked to fraud. Some improper payments are merely due to a lack of information submitted by a provider that is later corrected, he said.

Senators' Letter

In their letter to the committee, Carper and Coburn urged the panel to consider "strong measures" to curb fraud and abuse. They said Medicare and Medicaid lose tens of billions of dollars to waste, fraud, and abuse each year. "Without a doubt, waste and fraud from Medicare and Medicaid are a major drain from the federal budget," they said.

The lawmakers' bill, the Medicare and Medicaid Fighting Fraud and Abuse to Save Taxpayers Dollars Act (S. 3900), would:

- Put in place stronger penalties for Medicare and Medicaid fraud;
- Establish stronger prevention strategies to help phase out the practice of "pay and chase";
- Curb the theft of physician and beneficiary identities;
- Improve the sharing of fraud data across agencies; and
- Deploy cutting-edge technology to better identify and prevent fraud.

"The millions of Americans who depend on Medicare and Medicaid will benefit when these programs are strengthened through the prevention of waste and fraud," Carper and Coburn said.

Advocacy Groups Back Targeting Fraud

Beneficiary advocacy groups also want the deficit reduction panel to incorporate anti-fraud activities into its legislative proposal. In a Sept. 28 letter to the panel, the National Minority Quality Forum and 23 organizations, including AARP and the Medicare Rights Center, urged the panel to focus its cost-saving efforts on anti-fraud provisions.

In a press release, the group said that through improved program integrity and targeted efforts to eliminate fraud and abuse, significant savings could be achieved without harming the beneficiaries who depend on these services.

"We believe a top priority should be stopping the flow of dollars that now goes to criminals engaged in fraudulent and abusive practices—not increasing innocent beneficiaries' out-of-pocket costs or cutting the funds that go to meeting Medicare and Medicaid patient needs," the groups wrote.

News-At-A-Glance

DOC ARRESTED OVER LAB SCHEME: A Massachusetts physician was arrested and arraigned in state court Sept. 21, charged with running a Medicaid fraud kickback scheme that netted approximately $500,000 (*Massachusetts v. Kishore*). Punyamurtula Kishore, who owns and manages a network of 29 physician office laboratories and independent clinical laboratories, was charged in state superior court with one count of Medicaid kickbacks. He pleaded not guilty and bail was set at $150,000. Prosecutors charged that Kishore orchestrated a criminal kickback scheme, arranging for various sober homes to send patients to his network of laboratories, Preventive Medicine Associates Inc., to perform urine drug screen testing of Medicaid-eligible residents. Drug screens were billed to the state Medicaid program at a price of approximately $100 to $200, resulting in payments totaling $500,000, the state alleged. The investigation into the scheme remains ongoing.

STARK SETTLEMENT: A West Virginia health care corporation has resolved alleged Stark Act violations by entering into a $3.8 million settlement with the federal government, the Department of Justice (DOJ) announced Sept. 12. DOJ officials said they will now turn to the physicians for potential liability and are asking them to "self-report" Stark law violations. The agreement ends an investigation that Ohio Valley Health Services & Education Corp., based in Wheeling, W.Va., and its two hospitals submitted false claims for payment to Medicare and Medicaid from January 2005 to August 2010, said William J. Ihlenfeld, U.S. attorney for the Northern District of West Virginia. Ihlenfeld said the penalty is severe because the hospitals' compensation agreements with local physicians were improper under the Stark Act and involved significant amounts of money. The company and its hospitals cooperated with federal investigators, Ihlenfeld said, providing information needed to conclude the first phase of the investigation. Phase two of the case will involve pursuing the physicians involved and requiring that they return the prohibited payments and pay the statutory penalties.

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Kimberly Scott, Managing Editor; Dennis Weissman, Executive Editor; Heather Lancey, Designer; Beth Butler, Marketing Director; Dan Houder, Chief Operating Officer and Publisher

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