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New OIG Advisory Opinion Repeats Warning that Free Labeling Services Can Be Kickbacks

The government's longstanding aversion to labs providing free items or services to referral sources remains unaffected by changes in reimbursement methods. A laboratory sought an advisory opinion from the Office of Inspector General (OIG) regarding a proposal to provide dialysis facilities with free services, labeling test tubes and specimen collection containers used to collect specimens for testing at the lab. The OIG said such an arrangement would likely violate the Anti-Kickback Statute.

Facts of the proposed arrangement

Here is how the proposed arrangement would work:

- The lab performs testing services for dialysis facilities' patients;
- The lab provides free services to certain dialysis facilities for labeling; test tubes and specimen collection containers;

Continued on page 2

Labs Can Take Advantage of Transportation Anti-Kickback Safe Harbor

There are many benefits laboratories can't provide to beneficiaries or referral sources without violating the Anti-Kickback Statute. New changes to safe harbor regulations, however, allow labs to provide free transportation to Medicare beneficiaries under certain circumstances.

That's just one change affecting the Anti-Kickback safe harbors. Finalizing a proposed rule initially published in October 2014, the Office of Inspector General (OIG) revised the Anti-Kickback safe harbor regulations to afford "flexibility for providers and others to engage in health care business arrangements" that can "improve efficiency and access to quality care while protecting programs and patients from fraud and abuse." The main focus of the changes is to accommodate new health care delivery models in the age of value-based reimbursement systems and patient-centered care. Labs receive specific attention with regard to transportation in the final rule.

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New OIG Advisory Opinion Repeats Warning, *from page 1*

- Labeled tubes and containers are used to collect and send specimens to the lab for testing;
- Labeling is performed at lab not on site at the dialysis facility;
- The lab has discretion to choose which facilities receive this service and the lab admits its decision may be influenced by the need to obtain or retain business from a dialysis facility; and
- Without these free services, the dialysis facility would incur costs for labeling—which costs are not separately reimbursed by federal programs.

Not a new issue

The OIG has repeatedly expressed concern about laboratories providing free services or items to referral sources. In an oft-cited 1994 Fraud Alert, the OIG specifically called out labs that provide free items or services and indicated they raise an inference of kickbacks.

The OIG also addressed the same fact situation in a 2008 Advisory Opinion. At that time, dialysis facilities were paid composite rates. Now, dialysis facilities are paid via the End-Stage Renal Disease Prospective Payment System (since 2011)—a bundled payment that replaced the composite rate system. Under both payment systems, dialysis facilities were not separately paid for administrative tasks related to lab testing—such as labeling of test tubes and specimen containers.

OIG analysis

Once again, the OIG expressed its "longstanding and clear" position on labs providing free or discounted items or services to potential referral sources—"such arrangements are suspect and may violate the anti-kickback statute." This position was unaffected by the change in relevant payment systems between the 2008 and current proposals, the OIG said. Regardless of the payment system, the free services still saved the dialysis facilities from incurring a cost they'd otherwise bear on their own.

Additionally, the OIG pointed out that giving these labeling services to referral sources for free could also result in improper swapping arrangements. Because lab tests for dialysis services are bundled, discounts on dialysis-related lab services could induce the facility to send that lab its non-dialysis testing—which the lab can directly bill to Medicare or other federal programs.

It didn't help that in both the 2008 and current advisory opinion requests, the lab admitted its selection of which facilities got the free labeling services could depend "upon whether offering such services would be necessary to obtain or retain the business of a particular dialysis facility."

It seems the lab was possibly interested in getting a OIG statement that its competitors were offering kickbacks. The requesting lab in the 2008 and the current opinion notes some of its competitors are already providing these free services. The OIG warned that "comparable competitor arrangements" could likewise "run afoul of the anti-kickback statute."

Takeaway: OIG reiterates its disdain for labs providing free items and services to referral sources.

NIR

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Bipartisan Support Shepherds 21st Century Cures Act into Law

Demonstrating bipartisan support for precision medicine and and health care innovation—including genomics and other diagnostic innovations—the 21st Century Cures Act has become law. After the House of Representatives and Senate overwhelmingly voted to approve the legislation, President Obama signed it into law on Dec. 13, 2016.

"Passage of this important legislation is a milestone in improving the innovation ecosystem for medical technology and ensuring the availability of new life-saving, life-enhancing devices and diagnostics for patients."

— AdvaMed

Billions of dollars of funding will support precision medicine initiatives and other efforts to discover, develop and deliver treatments and cures for diseases such as cancer, Alzheimer's and rare diseases. As the American Clinical Laboratory Association pointed out in a 2014 letter to the Energy and Commerce Committee supporting the 21st Century Cures legislation, diagnostics "are an essential component to providing the most effective and highest quality care," with laboratory testing innovations helping physicians by "providing more accurate diagnoses, quicker; allowing physicians and patients to choose the best treatment, first and sooner."

There are four main parts to the legislation: Part I addresses discovery, innovation and opioid abuse; Part II addresses research and development, patient access to new products, protection for human research subjects, and data sharing; Part III addresses health care delivery, interoperability and telehealth; and Part IV addresses Medicare and Medicaid reforms. Here are some highlights of the legislation:

- $4.8 billion in funding for NIH; funds will in part support the Precision Medicine Initiative ($1.5 billion) and the Cancer Moonshot ($1.8 billion)
- $500 million for the FDA to modernize its regulatory efforts and secure the best talent
- Measures that promote electronic health records and interoperability so patient care is seamless
- $1 billion to states for opioid abuse prevention and treatment programs including improvement of drug monitoring programs

Summing up comments of many stakeholders in the life sciences industry, AdvaMed praised the law stating: "Passage of this important legislation is a milestone in improving the innovation ecosystem for medical technology and ensuring the availability of new life-saving, life-enhancing devices and diagnostics for patients."

But not all are happy with the legislation. An online opinion article appearing in *STAT* after the House of Representatives voted to pass the law, criticizes what it claims are weakened FDA oversight measures for new drugs and devices: "These provisions would unravel the FDA, turning it from the treatment watchdog it is today into a puppet of the pharmaceutical and medical device industry. If the 21st Century Cures Act is passed as written, clinicians could be given potentially deadly drugs and devices to prescribe to their patients, blessed by this new version of FDA approval."

Takeaway: Precision medicine initiatives get a significant show of support from both political parties.

Labs Can Take Advantage of Transportation Anti-Kickback Safe Harbor, *from page 1*

The OIG says it believes the changes "further the goals of access, quality, patient choice, appropriate utilization, and competition"

Safe harbor refresher

Safe harbors permit conduct that would otherwise likely violate the Anti-Kickback Statute. This protection is significant: as the OIG says in this final rule "[b]ecause of the broad reach of the statute, concern was expressed that some relatively innocuous commercial arrangements" could be subjected to prosecution as kickbacks. Violations of the Anti-Kickback Statute can subject the actor to felony charges, fines up to $25,000, imprisonment up to five years, imposition of civil monetary penalties, exclusion from participating in federal programs and False Claims Act liability. So Congress provided safe harbors and allows for them to be updated periodically to keep up with changing business practices and technology. Thus, this update. The OIG says it believes the changes "further the goals of access, quality, patient choice, appropriate utilization, and competition" yet avoid increasing costs, steering patients inappropriately or otherwise creating a risk that incentives will be tied to referrals. It also promises to continue to monitor the health care industry and consider future changes if needed to "foster high-quality, efficient, patient-centered care."

What's new in the final rule

Although the final rule does add some new safe harbors, it also incorporates changes into the safe harbor regulations that were included in already-enacted legislation. Here are highlights of what the rule does (see below for more detail):

- Incorporates into the safe harbor regulations the Anti-Kickback Statute exceptions included in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and the Patient Protection and Affordable Care Act (ACA)

Anti-Kickback Regulations Add new safe harbors or change existing safe harbors to:	**Civil Monetary Penalties Regulations** Revise "remuneration" definition to incorporate statutory exceptions for:
Correct the safe harbor for referral services to clarify that it doesn't protect payments for referral services based on volume or value of referrals to or "business generated by either party *for the other party*" (existing language inadvertently referenced "business generated by either party *for the referral service*")	Copayment reductions for certain hospital outpatient department services
Authorize cost-sharing waivers such as pharmacy waivers for financially needy beneficiaries and for emergency ambulance services provided by state or municipality-owned entities	Certain remuneration that "poses low risk of harm and promotes access to care" (like health care screenings)
Protect certain remuneration between Medicare Advantage Organizations and federally qualified health centers	Coupons, rebates or other retail reward programs meeting specific criteria
Permit discounts for drugs provided to beneficiaries under the Medicare Coverage Gap Discount Program	Certain remuneration for financially needy individuals
Allow free or discounted local transportation services that meet specific criteria	Copayment waiver for first fill of generic drug prescription

- Addresses the exceptions to the civil monetary penalties (CMP) law's definition of "remuneration" that were included in the Balanced Budget Act of 1997 (BBA) and the ACA
- Makes technical corrections to existing regulations
- Adds new safe harbors to the Anti-Kickback Statute regulations

Labs permitted to offer transportation

The new transportation safe harbor allows labs and other providers to offer free or discounted local transportation services to federal program beneficiaries. Under this safe harbor, transportation programs may offer: a) Transportation to and from a patient's home to provide access for that patient to a provider or supplier; or b) Vouchers for such transportation provided by another entity.

Some limitations apply to free or discounted transportation:

- Transportation can't be luxury, air or ambulance-level service;
- The transportation can't be advertised or used as a marketing tool;
- Transportation policies can't be influenced by past or anticipated volume or value of federal program business;
- Health care services or items can't be advertised or marketed during the transportation or at any time by drivers;
- Drivers or others involved in arranging the transportation can't be compensated based on "per-beneficiary-transported basis";
- Only established patients can be provided free transportation services;
- If one provider is offering free or discounted transport to another provider, the patient must be an established patient of both the transporting and receiving provider;
- Transportation must be for the purpose of accessing medically necessary items and services;
- The entity making the transport possible bears the cost of the transport and can't shift the cost to federal programs, other payers or individuals;
- Distance for transportation is limited to 25 miles from the provider in urban areas and 50 miles from the provider in rural areas (Distance is measured "as the crow flies"—i.e., it includes any destination within the 25 mile radius from the provider);
- Suppliers of items are not eligible to provide such transportation benefits;
- If a hospital transports a patient to a laboratory (or other specialty provider), the patient must be able to choose the lab and the hospital can't condition the transport on the patient selecting a lab in the hospital's network; and
- Policies must be implemented to ensure the provider consistently and uniformly administers the transportation program.

Laboratories almost were precluded from relying on this safe harbor. In the proposed rule, the OIG solicited comments on whether transportation for

OIG Updates Threshold for Nominal Value Gifts

Just as the OIG updated the regulations concerning Anti-Kickback safe harbors and civil monetary penalties to reflect current business practices and health care delivery models, the agency also updated the permissible thresholds for nominal value gifts to beneficiaries.

The civil monetary penalties law prohibits "remuneration" to federal program beneficiaries such as waivers of copayments or deductibles or providing any item or service for free or less than fair market value. But there are exceptions. One exception permits inexpensive gifts of "nominal value." Nominal value was previously interpreted to be no greater than $10 per item or $50 in the aggregate annually. Now, the OIG is updating those figures in a December policy statement setting nominal value as a retail value up to $15.00 per item or $75 in the aggregate per patient per year. Such gifts can't be cash or cash equivalents.

You can find the policy statement here: https://oig.hhs.gov/fraud/docs/alertsandbulletins/OIG-Policy-Statement-Gifts-of-Nominal-Value.pdf

laboratory services and home health services should be excluded from this safe harbor. The OIG had concerns that for those services such transportation was more likely to be offered in exchange for referrals. Ultimately, the OIG decided not to exclude laboratories or home health providers and only excludes suppliers of health care items (such as DME or pharmacy items).

Note that the rule requires free transportation only be offered to "established patients." The final rule explains, however, that established patients can include new patients who have contacted the provider to schedule an appointment. The eligibility trigger is that an initial appointment has been made. The key is that the patient has already chosen the provider, minimizing risk that free transportation service will influence provider selection. Thus, the patient doesn't have to have received health care services from the offering provider to be considered an established patient eligible for free transportation.

Finally, the safe harbor also allows eligible providers to offer shuttle services subject to most of the same criteria except that the shuttle must run on a set schedule and set route and shuttle schedules and stops can be posted without violating the no-marketing rule. Shuttles also aren't limited to providing access to medically necessary health care services or to transporting only established patients.

Takeaway: Revisions to Anti-Kickback safe harbor regulations recognize new legislation and provide flexibility for changing health care business practices.

Labs Beware: New Rules Impose Harsher Civil Monetary Penalties

It may be facing repeal but the Affordable Care Act (ACA) is not going down without a squawk. On Dec. 7, the Office of Inspector General (OIG) accomplished a key piece of ACA business by adopting harsher civil monetary penalties (CMPs) for Medicare/Medicaid fraud and abuse.

Background & Context

The Civil Monetary Penalties Law (CMPL), which dates back to 1981, allows the government to impose CMPs on providers for various offenses. CMPL violations can also get providers excluded from Medicare, Medicaid and other federal health care programs.

In 2010, Congress upped the ante by putting language in the ACA authorizing the OIG to impose CMPs for "false and fraudulent claims and similar misconduct." As if potential penalties under the False Claims Act, Anti-Kickback

Offenses Justifying Imposition of CMPS—Before & After

Original CMP Offenses	New CMP Offenses
■ Knowingly presenting or causing to be presented false claim for services ■ Knowingly giving or causing to be given false or misleading info reasonably expected to influence decision to discharge patient ■ Offering or giving remuneration to federal health care program beneficiary likely to influence receipt of reimbursable items or services ■ Arranging for reimbursable with entity excluded from a federal health care program ■ Knowingly or willfully soliciting or receiving payment for referral of beneficiary ■ Using a payment intended for beneficiary for another use	■ Failure to grant OIG timely access to reasonably requested records ■ Ordering or prescribing while excluded when excluded person knows or should know that item/service may be paid for by federal health care program ■ Making false statements, omissions or misrepresentations in an enrollment or similar bid application to participate in federal health care program ■ Failure to report and return an overpayment ■ Making or using false record or statement that is material to a false or fraudulent claim

Statute and/or Stark Law were not already tough enough, such violations would now expose labs to the risk of tack-on CMPs. But the ACA changes were not self-actuating. The OIG had to adopt specific regulations to put its new CMPs powers into effect. And that is what the Dec. 7 Regulation does.

4 Ways the New CMP Rules May Impact You

Here are the four aspects of the new rules that labs and other diagnostics providers should be concerned about, listed in order of importance.

1. More Ways for OIG to Sock Labs with CMPs

Change: Current rules authorize CMPs for six basic offenses; the new rules nearly double that total to 11, as summarized in the table above.

Practical Impact: Labs will be at greater risk of CMPs, particularly by the new overpayment offense. Under the new rules, failure to report and return overpayments within 60 days of identifying them can result in CMPs of up to $10,000 *per item or service* overpaid. The "per-service" language is especially scary for labs and other diagnostics providers that submit a high volume of low-value claims.

But it could have been much worse. In its Interim Rule, the OIG proposed penalizing providers $10,000 per day for each day they fail to report and return an overpayment. Fortunately for labs, the daily penalty did not make the final cut. However, the OIG did suggest that long delays in failing to report and return overpayments could be an "aggravating factor" justifying higher CMPs.

Overpayment is hardly the only concern. Other key new CMP offenses potentially affecting labs include:

- Not giving the OIG access to requested records;
- Use of false records or statements in false claims; and
- Accepting test orders from excluded providers.

2. CMPs Will Be Higher

Change: Not only will it become easier to get fined but fine amounts will be higher. You need a little context to understand why.

2015 CMP Adjustments

CMP Offense	Pre-Inflation Amount	Post-Inflation Amount	Percentage Increase
Offering remuneration to induce program beneficiaries to use particular providers	$10,000	$15,024	50.24%
Employing or contracting with excluded individual	$10,000	$14,718	47.17%
Knowing and willful solicitation, receipt, offer or payment for referring individual for service ... paid for by federal health care program	$50,000	$73,588	47.17%
Submitting or causing to be submitted claims in violation of Anti-Kickback Statute or Stark law	$15,000	$23,863	59.09%

The U.S. Department of Health and Human Services (HHS) is only one of many federal agencies that impose CMPs to punish violations of the laws under their jurisdiction. Some of these agencies have not done a good job of keeping their CMP schedules in line with inflation. So last year, Congress passed a law called The Bipartisan Budget Act of 2015 (BBA) mandating that federal agencies adjust their CMPs for inflation. The so-called "catch-up adjustment" had to be based on the difference between the CPI in October 2015 and the month the agency last increased its CMPs. Thereafter, agencies had to adjust their CMPs annually for inflation.

Practical Impact: HHS had not adjusted its own CMPs in decades. As a result, its "catch-up adjustments" were significant—as high as 150% in some cases. The table above shows key CMP adjustments that HHS made in the initial 2015 adjustment.

And because BBA mandates annual inflation adjustments, HHS had to increase the 2015 numbers again in 2016.

3. Risk of CMPs for Labs that Deal with Medicare Advantage and Part D Plans

Change: CMPs can be assessed against Medicare Advantage (MA) or Part D contracting organizations that:

- Enroll individuals without their consent
- Transfer enrollees from one plan to another without their consent
- Transfer enrollees for the sole purpose of making a commission
- Fail to apply with applicable marketing rules
- Employ or contract with persons who engage in marketing violations.

Practical Impact: Enrollment and marketing of health plans are not activities in which labs typically get directly involved. But the "employ or contract" offense may be broad enough to cover labs that do business with MA or Part D plans.

4. Clear Factors for Setting CMP Amounts

Change: The OIG has discretion to set the amount of CMPs. The Regulation adds transparency by listing the five factors the OIG will use to make such determinations, including:

- The nature and circumstances of the violation
- The person's "degree of culpability"

- Whether the provider has a history of offenses
- Other wrongful conduct
- Other matters "as justice may require."

Practical Impact: Knowing the aggravating and mitigating factors can help you manage CMP risks. For example, one insight that is especially worthy of noting is the OIG's acknowledgement that in assessing "degree of culpability," it will treat "appropriate and timely" corrective action as a mitigating factor. To get credit, though, the provider must disclose the violation under the OIG Self-Disclosure Protocol.

Takeaway: Three Ways to Protect Yourself

The new CMPs Regulation does not change the substance of your compliance obligations; but it does make the potential consequences of not living up to those obligations more costly. Some of the specific things to put on your to-do list:

1. Minimize risk of CMPs for overpayments by ensuring your lab meets the requirements of the Feb. 2016 CMS Final Rule on complying with the 60-day deadline for returning Medicare overpayments (*G2 Compliance Advisor*, April 2016).
2. Take advantage of the new "degree of culpability" mitigating factor for CMPs by familiarizing yourself with and, if necessary, implementing the OIG Self-Disclosure Protocol.
3. Avoid CMPs for employing or contracting with excluded providers by performing background checks on job applicants, current employees and referring physicians.

DOJ Surveys False Claims Victories for 2016

As we close out the calendar year, the U.S. Department of Justice (DOJ) reflected on its successes for the fiscal year 2016 (FY 2016) which ended Sept. 30, 2016. Principal Deputy Assistant Attorney General Benjamin C. Mizer announced in mid-December that the DOJ achieved over $4.7 billion in False Claims Act (FCA) recoveries. Highlights for FY 2016:

- $4.7 billion total recovered in settlements and judgments from civil fraud or false claims cases, which includes $2.5 billion from health care cases (not including state Medicaid losses)
- $4.7 billion recovery is third highest annual recovery in FCA history
- Fiscal year average is now $4 billion for period 2009-2016
- $31.3 billion has been recovered between 2009-2016
- 2016 is the seventh consecutive year recoveries exceed $2 billion
- 702 qui tam (whistleblower) lawsuits were filed in FY 2016
- $2.9 billion recovered via qui tam/whistleblower suits in FY 2016
- Whistleblowers received $519 million in FY 2016

- Aggregate *qui tam* recoveries for January 2009 through end of FY 2016 were $24 billion in settlements and judgments and more than $4 billion in whistleblower awards
- January 2009-FY 2016 total health care fraud recoveries are $19.3 billion—more than half of all recoveries achieved in the past 30 years

The DOJ highlighted health care entities caught up in these recoveries, including drug and device companies, hospitals, nursing homes, physicians and laboratories. Among the health care cases spotlighted is the Millennium Health (formerly Millennium Laboratories) settlement for $260 million resolving allegations of unnecessary urine drug and genetic testing and providing free items to physicians referring expensive lab tests.

It's not just all about numbers though. In addition to these high profile settlements, U.S. Health and Human Services Inspector General Daniel R. Levinson emphasized a commitment to aggressive enforcement at all levels and the collateral benefits in addition to the dollars recovered: "Beyond those significant settlements, though, my agency works to improve voluntary observance of federal laws through corporate integrity agreements addressing compliance weaknesses and self-disclosures that encourage health care providers and other entities to voluntarily report suspected violations." The DOJ also continued to emphasize the need to hold accountable not just entities, but the individuals running them—citing what is commonly referred to as the Yates memorandum, issued in September 2015.

Congress Wants Medicare Fraud Caught Before it Happens

Despite the Department of Justice's announcement of $4.7 billion in recoveries for FY 2016, there is still concern that more needs to be done before false claims are paid. In September 2016, Members of Congress sent a letter to Andrew Slavitt, Acting Administrator of the Centers for Medicare and Medicaid Services stating: "The billions of dollars lost to Medicare fraud each year underscore the importance of stopping potentially fraudulent payments before they are made." The letter eschews the so-called "pay and chase" efforts to recover improper payments after the fact and supported increased use of methods such as the Fraud Prevention System (FPS), using predictive analytics to "identify claims and providers that present a high fraud risk to the Medicare program." The Congressional members expressed a concern that despite the use of FPS, CMS was still relying "too heavily" on efforts to identify and recover improperly paid claims rather than preventing them from happening. The letter also requested information regarding the types of schemes FPS has identified and total investigations for the past three years.

Among the individuals spotlighted by the DOJ as being held personally liable for alleged false claims, nearly half were individuals with connections to laboratory testing, including:

- Dr. Jonathan Oppenheimer, a former owner and executive of a Nashville drug testing laboratory, who agreed to a $9.35 million settlement. The physician and the lab agreed to be jointly and severally liable for the settlement amount and the physician was excluded from participating in federal health care programs for five years. The government alleged that the lab and physician violated restrictions in the Anti-Kickback EHR safe harbor and Stark EHR exception.
- Gottfried and Mieke Kellerman, founders of Pharmasan Labs, Inc. and NeuroScience, Inc., along with the companies, agreed to pay $8.5 million to settle allegations the lab submitted claims for ineligible food sensitivity tests to Medicare.
- Dr. David G. Bostwick founder and former owner and CEO of Bostwick Laboratories

agreed to a $3.75 million settlement resolving allegations his laboratory violated the False Claims Act by billing for medically unnecessary cancer detection tests and provided incentives for physician referrals.

- Urologists Dr. David Spellberg and Robert A. Scappa, D.O. settled allegations of medically unnecessary fluorescence in situ hybridization, or "FISH," testing—Spellberg settled for more than $1 million.

Takeaway: The DOJ's reporting of FY 2016 fraud recoveries indicates large scale and individual enforcement efforts continue unabated and that laboratory testing is a fruitful target for enforcement agencies.

Semiannual OIG Report to Congress Outlines Challenges & Successes

The Office of Inspector General's latest semiannual report to Congress provides a guide to the enforcement priorities the agency will continue to pursue, and proclaims its achievements in oversight and enforcement.

The OIG semiannual report notes that together with the Top Management and Performance Challenges report (see box), the agency has outlined areas of improvement for the Department of Health and Human Services. In particular, the agency cautioned: "Program integrity must be a top priority as HHS programs grow in size and complexity and incorporate new paradigms focused on value, quality, and patient-centered care."

OIG continues to expand its use of data analytics to strengthen oversight efforts.

Here are the main takeaways labs and pathologists should be aware of from the OIG report to Congress:

- **Strike Force continues aggressive enforcement.** This past year, the Health Care Fraud Strike Force achieved its largest takedown involving $900 million in false billing, 301 individuals targeted and 350 OIG agents. Most of the providers involved home health care but this is another warning to the rest of the provider community that such large scale enforcement efforts are not abating and continue to be very profitable for the government.
- **Data analytics are "go to" enforcement tool.** As the OIG highlights in discussion of the Takedown success, data analytics continue to be a major investigative tool for the OIG and the Strike Force. "OIG continues to expand its use of data analytics to strengthen oversight efforts." The report notes a $9.3 million settlement with a Tennessee lab and a physician regarding alleged false claims to Medicare for drug testing and non-covered FISH testing. The drug tests were allegedly referred to the lab by physicians to whom the lab donated money for purchasing EHR systems.
- **Data isn't just for enforcement.** The OIG emphasized "the critical role that complete, accurate, timely, and secure data must play in strengthening the performance of HHS programs" and renewed its recommendation that "CMS improve Medicare and Medicaid provider data systems" including security of those systems.

Labs Among HHS' Top 10 Management Challenges

The U.S. Department of Health and Human Services (HHS) Office of Inspector General spotlighted 10 top management challenges it says the HHS is facing and laboratory issues figure prominently in the list.

The #1 challenge listed is Ensuring Program Integrity for the Medicare program which the OIG says includes three categories: reducing improper payments, preventing and addressing fraud and abuse, and "Fostering Prudent Payment Policies." With regard to payment policies, the agency notes that the Centers for Medicare & Medicaid Services has several tasks to complete for implementation of the Protecting Access to Medicare Act of 2014 (PAMA) and "[t]imeframes for some of these tasks are tight." The OIG also reiterates its concern about "risks to payment accuracy" because the agency will be relying on laboratories to self-identify who should report and self-attest to the accuracy of their own reporting.

Despite acknowledging that the agency has made "substantial strides" in fighting fraud, the OIG says "more must be done to protect Medicare from fraud, waste and abuse and extend the solvency of the program."

- **Program integrity is a top priority.** That's because of the growth of HHS programs and "new paradigms focused on value, quality, and patient-centered care."
- **Top OIG fraud concerns include labs.** Fraud investigations continue to focus on medically unnecessary services and kickbacks among other issues. Lab testing was specifically identified among the types of fraud schemes that are a top OIG concern.

Takeaway: The OIG's latest report on its oversight efforts highlights large-scale investigations and recoveries as well as areas for improvement in HHS program integrity.