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New OIG Rules Make It Easier to Sock Labs with 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 Statute and/or Stark

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Brief Your CEO: The New Anti-Kickback Safe Harbors & Their Impact on Your Lab

If, like many lab managers, you are preparing to brief your CEO on significant regulatory changes from 2016 that are likely to impact business in 2017, be sure that the finalized revisions to the Anti-Kickback Statute (AKS) safe harbors are part of your agenda. Here are the key points about the final rule, which was issued by the Office of Inspector General (OIG) on Dec. 7, to cover in your briefing.

The AKS & Safe Harbors

First, set the legal context. Remind your CEO that the AKS makes it a criminal offense for labs to offer or pay "remuneration" to physicians for Medicare referrals. "Remuneration" is interpreted broadly to include not just cash but benefits such as gifts, supplies and services offered for free or less than fair market value. In addition fines of up to $50,000 + three times the remuneration amount, civil monetary penalties and imprisonment of up to five years, AKS violations can result in liability under other federal laws including the False Claims Act and Stark Law.

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Brief Your CEO: The New Anti-Kickback Safe Harbors, *from page 1*

Many of the common business arrangements between labs and referring physicians raise potential kickback concerns. The good news is that the AKS and its regulations carve out "safe harbors" allowing transactions that would otherwise trigger kickback concerns provided that the parties take the prescribed precautions. Without safe harbors, it would be almost impossible for labs, hospitals and other providers to conduct business with referral sources. Key safe harbors affecting labs and referring physicians include:

- Bona fide employment relationships
- Personal services and management contracts
- Discounts
- Fair market value space or equipment rentals

Why the OIG Revised the Safe Harbors

Next, describe the regulatory context. Explain that safe harbors need to be constantly updated to keep up with new legislation, technology and business practices. The need for the latest revision arose as a result of legislation dating as far back as 1997 when a pair of new arrangements became offenses under the Civil Monetary Penalties Law:

- Beneficiary inducements, that is, offering or providing remuneration to Medicare or Medicaid beneficiaries to influence their selection of a provider, such as by waiving co-payments or offering free transportation; and
- Gainsharing, that is, certain incentive payments made to physicians by hospitals, HMOs and competitive medical plans.

Although the CMP Law made some limited exceptions, there was also a need to address not only these arrangements in the AKS safe harbor regulations. So, on Oct. 3, 2014, the OIG issued a proposed rule creating new AKS safe harbor protection for beneficiary inducements and gainsharing and addressing other legislative changes made under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and the Patient Protection and Affordable Care Act (ACA). According to the OIG, the final rule, which is almost identical to the proposed version, "further[s] the goals of access, quality, patient choice, appropriate utilization, and competition" while still preventing "increasing costs, steering patients inappropriately or otherwise creating risk of incentives being tied to referrals."

New Safe Harbor for Free Transportation

Next explain the final rule and its impact on business. Start with the change that is likely to have the most direct impact on labs: the new safe harbor covering "free or discounted local transportation services provided to" federal program beneficiaries. This new safe harbor covers both:

- Actual transportation to and from a patient's home so as to provide the patient access to a provider or supplier; and
- Transportation vouchers.

G2CA

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Of course, all safe harbors have strings attached. One of the key limitations is that transportation may only be offered to established patients. But that does not necessarily mean that the patient must have previously received services from the provider. The final rule defines established patients as including new patients who contact the provider to schedule an appointment. Once the initial appointment is made, those new patients qualify as established patients for purposes of the safe harbor.

Be sure to tell your CEO about the other 10 limitations that apply to the new free transportation safe harbor:

- It does not apply to certain types of transportation, i.e., luxury, air and ambulance level service
- The lab may not advertise that it provides free or discounted transportation or use it as a marketing tool;
- Health care services or items may not be advertised or marketed during the transportation or at any time by drivers;
- Drivers and others involved in arranging the transportation may not be compensated on a "per-beneficiary-transported basis";
- Transportation must be for the purpose of accessing medically necessary items and services;
- The entity making the transport possible must bear the cost of transport and may not shift those costs to federal programs or other payers or individuals;
- The maximum distance of transportation to the lab is 25 miles in urban areas and 50 miles in rural areas, measured "as the crow flies" within a radius of that mileage;
- The safe harbor does not apply to suppliers of items;
- If a hospital transports a patient to a lab (or other specialty provider) the patient must be able to choose the specific provider and the hospital may not condition transport on the patient selecting a lab in the hospital's network;
- Consistent policies must be implemented to administer the transportation program.

It is important to stress that the OIG was considering excluding lab and home health services from the safe harbor because of concerns that transportation offered by these providers would be more likely to induce referrals. But after soliciting comments, the OIG ultimately decided not to omit labs and home health providers from the final rule.

A Big Month for Anti-Kickback Regulation

The end of November and early December was an unusually busy period as far as OIG anti-kickback activity is concerned:

November 28: The OIG issues Advisory Opinion (16-12), nixing a proposed arrangement involving a lab's provision of free specimen labelling to select dialysis facilities due to kickback concerns.

December 7: More than two years after proposing it, the OIG finally issues a final rule creating new anti-kickback safe harbors and revising existing ones. (See the story above.)

December 7: The OIG issues a new Policy Statement adjusting its thresholds for "nominal value," i.e., gifts or items that do not constitute "remuneration" banned by the anti-kickback statute because their value is so low:

- **Previous thresholds:** $10 per item and $50 in the aggregate (per patient per year)
- **Updated thresholds:** $15 per item and $75 in the aggregate

The 5 Other Changes

Finally, brief your CEO on the other new safe harbors and/or revisions to existing safe harbors contained in the Final Rule:

1. Technical Correction to "Referral Services" Safe Harbor

The AKS includes a safe harbor allowing participants to make payments to a referral service as long as the payment is: Based solely on the costs of operating the referral service and not on the volume or value of referrals to or business generated by "either party for the referral service" for which payment may be made under Medicare.

The final rule makes a technical change to how the rule is worded. Specifically, it eliminates the phrase "by either party for the referral service," substituting "by either party for the other party." The change was made to eliminate the ambiguity in the current language that could be interpreted as meaning referral services may adjust their fees on the basis of volumes of referrals made to participants, the OIG explains.

2. New Safe Harbor for Pharmacy Cost-Sharing Waivers

The final rule creates new safe harbors allowing providers to waive or reduce Medicare/Medicaid beneficiary coinsurance/deductible amounts. One of these covers waivers or reductions by pharmacies of cost-sharing obligations under Medicare Part D and other federal health care programs, e.g., physician copayments for Part B drugs, as long as:

- The waiver/reduction is not advertised or used for marketing;
- The pharmacy does not routinely waive cost-sharing; and
- The pharmacy either:
  - Determines in good faith that the beneficiary has a financial need; or
  - Fails to collect cost-sharing amounts after making reasonable efforts to do so.

3. New Safe Harbor for Emergency Ambulance Cost-Sharing Waivers

Another new safe harbor permits waiver or reduction Medicare/Medicaid beneficiary coinsurance/deductible amounts for "emergency ambulance services" furnished by a Part B ambulance provider or supplier owned or operated by a state or its political subdivision (or a tribal health program), provided that:

- Providers offer the waiver or reduction on a uniform basis;
- Waivers and reductions are not based on patient-specific factors other than residency; and
- Providers do not claim the waiver or deduction amount as bad debt.

4. New Safe Harbor for Medicare Advantage/Federally Qualified Health Center (FQHC) Remuneration

The final rule creates an AKS version of a safe harbor contained in the MMA covering remuneration between a Medicare Advantage organization and a FQHC, as long as the remuneration is provided under a proper written agreement.

5. New Safe Harbor for Medicare Coverage Gap Drug Discounts
Section 3301(d) of the ACA allows for discounts on Part D drugs to beneficiaries under the Medicare Coverage Gap Discount Program (MCGDP). The final rule establishes an AKS version of "donut hole" discount safe harbor that applies as long as the drug manufacturers is in full compliance with MCGDP requirements.

Takeaway: Make sure you let your lab officers know about the new Anti-Kickback Statute safe harbors just adopted by the OIG. For most labs, the most important new safe harbor is the one allowing providers to offer free or reduced cost transportation between a Medicare/Medicaid beneficiary's home and the facility, provided that specific conditions are met. The final rule also creates four other new safe harbors, two of which allow for waiving or reducing beneficiary copayments/deductibles in certain situations.

Labs IN COURT

A roundup of recent cases and enforcement actions involving the diagnostics industry.

BLS Bribery Scheme Claims another Physician. **Case:** A New York internist became the third physician indicted in the Biodiagnostic Laboratory Services (BLS) bribery scheme. The Justice Department claims that the internist received tens of thousands of dollars' worth of bribes from BLS employees over a two-year period in return for referring patient blood samples to the now-defunct New Jersey lab and at one point, even demanded and got an increase to his monthly payment for luring a third physician into the scheme. **Significance:** The BLS case is a perfect illustration of the ruin that a kickback scheme can inflict upon all involved. In June, BLS had to shut down and forfeit all its assets after pleading guilty to kickback charges. The investigation has also generated what is believed to be a record number of prosecutions against medical professionals in a bribery case, yielding 41 guilty pleas, 27 of them from physicians. One physician has been sentenced to 37 months in prison and the other two await trial. (For more on the BLS sentencing, see *GCA*, July, 2016).

Texas Lab Fined $3.75 Million for Inflating Mileage Claims. **Case:** In July 2014, a former employee filed a qui tam lawsuit against the owners of Elite Lab Services. Among other things, she claimed that over a four-year period the Texas lab charged Medicare for tens of thousands of miles that its personnel never actually drove. On Dec. 13, the owners agreed to settle the case by paying $3.75 million, 21% (or $787,500) of which will go to the whistleblower, and admitting they submitted false claims to Medicare. **Significance:** As with so many whistleblower cases, this lawsuit was one the lab might have been able to prevent. The employee approached the owners to voice her concerns over its mileage billing practices. But for whatever reason, the owners squandered the opportunity to correct the problem. The employee resigned and took up the litigation option. (For guidance on avoiding the same mistakes and turning a potential whistleblower lawsuit into a positive and constructive compliance initiative, see "Whistleblowers Can Be Your Best Friend," *GCA*).

Civil False Claims Charges against Lab Owner Jailed for Evading Medicare Pre-Payment Review. **Case:** Troubles continue for the New Jersey owner of a diagnostic testing company jailed for evading Medicare pre-payment review. Now, the government is suing him to recover false claims. The story begins in 2009 when the Medicare contractor placed a cardiologist affiliated with the testing company on pre-payment review to ensure he was properly documenting Medicare claims. The lab owner was charged with deliberately evading pre-payment review by submitting claims through his company and a company owned by his brother—making it look like the services were performed by the companies rather than the cardiologist—and then siphoning off Medicare payments received to himself and the cardiologist. In June 2015, the owner pleaded guilty and was sentenced to a prison sentence of 12 months. **Significance:** The owner's ordeal is a reminder that False Claims Act violations carry the risk of both criminal and civil liability. In other words, there is no "double jeopardy" bar against the government's bringing a civil lawsuit for money damages against the owner for the same violations that led to his criminal conviction a year earlier—although it is unclear why the government in this case did not follow its usual course and pursue the criminal and civil case in a single proceeding. (For more on the case, see "Physicians Sentenced for Diagnostic Testing Schemes," *National Intelligence Report*, June 4, 2015.)

New OIG Rules Make It Easier to Sock Labs with Civil Monetary Penalties, *from page 1*

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.

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 items or services 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

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.

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%

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.

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 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.

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.

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.

EMERGING COMPLIANCE RISKS

Failure to Properly Document Sleep Study Tests

If your lab performs sleep studies on Medicare patients, beware. It is now a high-priority target for federal fraud and abuse enforcement. Here is a look at the risk you face and what you can do to manage it.

The most common code for billing sleep disorder tests is HCPCS 95810.

Who Is At Risk?

Target providers include independent and hospital labs that perform polysomnography, a sleep study in which patients sleep overnight while connected to sensors measuring brain waves, blood oxygen flow and other parameters. The study is commonly used to diagnose obstructive sleep apnea (OSA) and evaluate the effectiveness of using positive airway pressure (PAP) devices to manage the condition.

When the polysomnography indicates that a patient has a sleep disorder the lab will often conduct a PAP titration study as well. Patients may also receive a PAP device for home use after the titration study. In so-called split-night cases, *both* studies are performed on the same patient on the same night—the polysomnography followed a few hours later by the PAP titration.

Medicare Coverage & Billing Rules

The most common code for billing sleep disorder tests is HCPCS 95810. As with most diagnostic services, polysomnography consists of two components:

- The technical component covering administration of the test, signified by HCPCS modifier code -TC; and
- The professional component covering the provider's interpretation of the test results, signified by code -26.

Failure to list either modifier is an indication that the lab is billing globally for both the technical and professional components. HCPCS 95811 is the code for both PAP titration and split-night services.

OIG Lowers the Boom on Sleep Clinics

Incomplete and missing documentation of sleep testing procedures has become a recurring problem for sleep testing labs, one that has gathered increasing attention from the Office of Inspector General (OIG). The seal was broken in a January 2013 case in which Florida-based American Sleep Medicine LLC agreed to pay $15.3 million to settle claims for falsely billing Medicare and TRICARE for sleep diagnostic services. Since then, the OIG has zeroed in on billing for sleep testing, even listing it as an item in its 2017 Work Plan.

The most recent target was another Florida clinic called Sleep Health. The OIG audited 100 random Medicare patients who had received polysomnography services over two years. The findings, listed in the OIG's September report: The Fort Myers-based clinic received $48,934 in overpayments—$1,431,339 in total when extrapolated over the 3-year recovery period.

In addition to paying back that money, the OIG called on Sleep Health to work with the Medicare administrative contractor (MAC) to return the es-

timated $345,593 in overpayments it allegedly received outside the 3-year recovery period.

Takeaway: Ensure Proper Billing and Documentation of Sleep Tests

According to Local Coverage Determination (L29949), before sleep testing is performed, two sets of documentation are required:

The treating physician must perform a face-to-face clinical evaluation documenting the need for testing that includes a minimum of three things:

- The patient's symptoms and sleep history;
- An Epworth sleepiness scale; and
- A focused cardiopulmonary and upper airway evaluation.

The treating physician must then write an order for the study.

The lab that performs the study must keep a record of the attending physician's face-to-face evaluation and written order.

Thus, in the Sleep Health case, the OIG identified a pattern of what it believed to be documentation breakdowns affecting 63 patients with 143 corresponding lines of service. For 116 lines of service, the problem was that the treating physician's clinical evaluation was incomplete because at least one of the three required elements was missing. For 27 lines of service, the OIG contended that there was no documentation of the clinical evaluation, order or technician's report.

Takeaway: It should be stressed that Sleep Health has vigorously refuted the OIG's findings. But more often than not, providers accused of improper billing end up settling these cases rather than risk slugging it out in court. And even if Sleep Health ultimately is vindicated, simply having to defend against these charges is likely to take a toll. Bottom Line: If you bill Medicare, Medicaid or another federal health care program for polysomnography services, make sure you implement controls to ensure those tests are adequately documented.

ENFORCEMENT TRENDS

5 Insights from the OIG Semi-Annual Report

You can always count on OIG semiannual reports to Congress for two things: self-congratulation and insight into the enforcement priorities for the next six months. The most recent edition, published on Oct. 31, covers the period between April 1 and Sept. 30, 2016. Here are the five key takeaways for labs and pathologists.

1. Continuation of Aggressive Enforcement by Strike Force

In the 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. Although home healthcare was the primary target, the program's current success and profitability is likely to foster new efforts targeting other providers, including labs.

The report notes that fraud investigations continue to focus on "patient harm; billing for services not rendered, medically unnecessary services, or upcoded services; illegal billing, sale, diversion, and off-label marketing of prescription drugs; and solicitation and receipt of kickbacks, including illegal payments to patients for involvement in fraud schemes and illegal referral arrangements between physicians and medical companies."

2. Continued Reliance on Data Analytics

As noted in the report's discussion of the Takedown, data analytics continue to be a major investigative tool for the OIG and Strike Force. "OIG continues to expand its use of data analytics to strengthen oversight efforts." One enforcement example included a $9.3 million settlement with a Tennessee lab and a physician over alleged false claims to Medicare for drug testing referred to the lab by physicians to whom the lab donated money for purchasing EHR systems and for false claims for non-covered FISH testing.

3. Use of Data Beyond Enforcement

The OIG emphasizes "the critical role that complete, accurate, timely, and secure data must play in strengthening the performance of HHS programs" and renews its recommendation that "CMS improve Medicare and Medicaid provider data systems" including security of those systems.

4. Prioritization of Program Integrity

Program integrity "must be a top priority," says the OIG, because of the growth of HHS programs and "new paradigms focused on value, quality, and patient-centered care."

5. What the Fraud Investigators Are Looking for

The report notes that fraud investigations continue to focus on "patient harm; billing for services not rendered, medically unnecessary services, or upcoded services; illegal billing, sale, diversion, and off-label marketing of prescription drugs; and solicitation and receipt of kickbacks, including illegal payments to patients for involvement in fraud schemes and illegal referral arrangements between physicians and medical companies." Lab testing is specifically identified as an area of concern for fraud schemes.

2016 Enforcement By the Numbers

The OIG report lists the following statistics on the agency's enforcement efforts in fiscal year 2016:

- Over $5.66 billion in expected recoveries;
- 844 criminal actions against individuals or entities relating to HHS programs;
- 708 civil actions, including false claims and unjust-enrichment lawsuits, CMP settlements and "administrative recoveries related to provider self-disclosure matters";
- Exclusions of 3,635 individuals and entities;
- Strike Force charges filed against 255 individuals or entities, 207 criminal actions and $321 million in investigative receivables.

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.

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."

The rest of the Top 10 management challenges listed by HHS:

2. Oversight of Medicaid and managed care;
3. Secure and efficient use and exchange of electronic health information;
4. Improved financial and administrative management of HHS programs which total $1 trillion in costs;
5. Oversight of more than $400 billion in HHS grants benefiting public health;
6. Addressing the misuse of drugs under Medicare Part D and Medicaid;
7. Protecting vulnerable populations with regard to safety and quality of health care services, including children and patients of nursing homes, hospice and home health programs;
8. Operating and overseeing the health insurance marketplaces;
9. Managing reforms to health care delivery and strengthening Medicare Advantage;
10. Ensuring the safety of food, drugs and medical devices.