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Enforcement Trends: Federal False Claims Act Recoveries Hit 5-Year High

For more than a decade, enforcement of the federal false claims act was a government cash cow. But in recent years, investment returns on the activity actually declined. That trend came to an end last year, as FY 2019 recoveries ticked slightly up. And despite the COVID-19 pandemic and continued sequestration of enforcement funds, the growth continued in FY 2020. In fact, federal Health Care Fraud and Abuse Control Program (Program) recoveries for the year reached nearly $3.1 billion, the highest return since 2016. Here's a briefing for lab compliance managers on the recent OIG report and what it says about the current state of federal health care fraud enforcement.

ROI Increases to $4.30

The Program was created as part of the *Health Insurance Portability and Accountability Act of 1996* (HIPAA) under the joint direction of the Attorney General and HHS Secretary, acting through the OIG, to coordinate federal, state and local law health care fraud and abuse enforcement activities. The Annual Report describes the Program's financial performance in the previous

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Kickbacks: OIG Sheds Light on When Price Reductions Must Meet Discounts Safe Harbor

Labs that offer discounts of any kind to referring physicians run the risk of liability under the Anti-Kickback Statute (AKS) and other federal laws. However, new OIG Advisory Opinion No. 21-06 gives the greenlight for a durable medical equipment (DME) manufacturer to provide reduced prices to hospitals that agree to carry out duties the manufacturer usually compensates third parties to provide. And while the proposed arrangement doesn't involve lab services, the Opinion may have implications for labs.

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Enforcement Trends: Federal False Claims Act Recoveries Hit 5-Year High, *from page 1*

fiscal year. While the narrative is somewhat helpful, the enforcement and recovery statistics constitute the real value of these annual reports, at least from a lab compliance officer's perspective. Tracking these numbers over a three-year period gives a good sense of the current energy and direction of federal fraud activity, including with regard to labs.

Among the most significant metrics in the annual report is Program ROI, which measures how much money the Program returns for every dollar invested. Program ROI is calculated by dividing the total monetary results to the federal government in judgments, sentences, settlements and other recoveries (not including relator payments in *qui tam* lawsuits) by the annual appropriation for the Program Account in a given year (not including portions of CMS funding dedicated to the Medicare Integrity Program). Because the annual ROI tends to vary from year to year depending on the number and type of cases that are settled or adjudicated during the year, DOJ and HHS use a three-year rolling average ROI for results contained in the report.

And since FY 2013 when ROI peaked at $8.10, ROI has been trending steadily down, with five consecutive years of decline. FY 2019 finally saw the losing streak come to an end, with ROI increasing from $4.00 to $4.20 in 2019. The upward movement continued this year, with the three-year rolling average ROI reaching $4.30 in FY 2020.

Annual Program ROI, FY 2013 to FY 2020 (3-Year Rolling Average)

FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020
$8.10	$7.70	$6.10	$5.00	$4.20	$4.00	$4.20	$4.30

By the Numbers

During FY 2020, the federal government won or negotiated nearly $3.1 billion ($3,075,834,684) in health care fraud judgments and settlements. That's up from $2.6 billion in FY 2019, even though the number of convictions during the same period actually declined from 528 to 440. Civil actions, which have traditionally been the cash cow of federal health care fraud enforcement efforts, were up sharply in FY 2020, from 1,112 to 1,498, which portends higher recovery levels in the years ahead when these new actions yield judgments and settlements. However, exclusion numbers were fell off by nearly 25 percent to 2,148.

Metric	FY 2020	FY 2019	FY 2018
Total recoveries	$3.1 billion	$2.6 billion	$2.3 billion
New DOJ criminal health care fraud investigations	1,148	1,060	1,139
New DOJ Civil Health care fraud investigations	1,498	1,112	918
New Criminal cases filed	578	485	572
Convictions	440	528	872
Exclusions issued by OIG	2,148	2,640	2,712

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The increases in most of the enforcement metrics occurred even though sequestration reduced the enforcement funding available to the DOJ, FBI, HHS and OIG. A total of $11.0 million was sequestered from the Program in FY 2020, for a combined total of $150.6 million in mandatory funds sequestered in the past eight years. Including funds sequestered from the FBI ($70.0 million in the past eight years), $220.6 million has been sequestered from mandatory Program funds since FY 2013.

Takeaway

Although labs are a perennial favorite target for enforcers, they were especially prominent for the wrong reasons in FY 2020. Genetic and other testing labs played a prominent role in the Operation Rubberstamp national takedown of telemedicine fraud, the biggest takedown collaboration in history.

In addition to the usual kickback and Stark recoveries that take place each year, enforcers targeted COVID-19 add-on tests, i.e., high-priced and medically unnecessary tests carried out on patients tested for SARS-CoV-2, including the Respiratory Protection Panel (RPP), antibiotic resistance tests, genetic testing and cardiac panels CPT codes. "Providers are also billing respiratory, gastrointestinal, genitourinary, and dermatologic pathogen code sets with the not otherwise specified code CPT 87798," according to the report.

Enforcement Update: CMS Proposes Higher Fines for Hospital Price Transparency Noncompliance

The Center for Medicare and Medicare Service's (CMS) new price transparency rules requiring hospitals to make pricing information available for 300 shoppable services in a consumer-friendly format officially took effect on Jan. 1, 2021. However, many hospitals are still not following the new rules. So, now CMS is proposing to increase the penalties for noncompliance.

The Hospital Price Transparency Rules

Like many businesses, hospitals have treated the prices they charge for services as proprietary information that they don't disclose to patients or the public. In an effort to empower health care consumers, in 2019, CMS finalized a rule requiring hospitals to end this practice and make their prices public. The price transparency rule, which survived legal challenges from hospitals, requires hospitals to do two basic things:

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- Publish discounted cash prices for all services, including both what they charge uninsured patients and the payer-specific rates they negotiate with insurers, health plans, etc.; and
- Display price data in a consumer-friendly manner allowing consumers to make service-specific cost comparisons across hospitals, including expected out-of-pocket costs, for 300 "shoppable services" that can be scheduled in advance.

Hospitals Drag Their Heels

Despite the risk of penalties of up to $300 per day, studies suggest that the majority of hospitals haven't been complying with the new price transparency rules. According to a June 14 *JAMA* report, of the 200 random hospitals analyzed, 83 were found to be noncompliant with at least one of the rules' major requirements. The report also found that:

- Only 33 reported payer-specific negotiated rates and only 30 reported discounted cash prices in a machine-readable file; and
- Only 52 hospitals offered a price estimator tool for the required 300 shoppable services, of which 23 posted payer-specific negotiated rates in a machine-readable file.

Of the 100 highest revenue hospitals in the *JAMA* study:

- 75 were noncompliant with at least one requirement;
- 35 reported payer-specific negotiated rates; and
- 40 reported discounted cash prices in a machine-readable file.

A week after the *JAMA* report, the *American Journal of Managed Care* published a study evaluated the public websites of the 20 hospitals listed in a 2020-2021 *US News & World Report* honor roll between Feb. 1 and Feb. 14 finding that 60 percent displayed their cash prices and 5 percent displayed their minimum negotiated charges on their public websites.

The authors focused on two imaging studies—brain MRI and abdominal ultrasound and three hospital services—cardiac valve surgery, total joint replacement and vaginal childbirth. For each, the authors determined whether the discounted cash price and minimum negotiated charge were displayed and, if displayed, what the prices were. The findings:

- 13 of the hospitals (65 percent) displayed the cash prices for MRI and ultrasound;
- 8 (40 percent) displayed cash prices for valve surgery;
- 10 (50 percent) published their cash prices for joint replacement; and
- 10 (50 percent) posted cash prices for childbirth services.

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Early Returns Support the Theory of Price Transparency

Advocates of transparency contend that knowing the prices in advance will empower consumers to shop for services and save money. One of the underlying assumptions of that theory is that there really is a differential in what hospitals charge for the same services. The June 21 *American Journal of Managed Care* study furnishes evidence to support that theory. Thus, the study authors found that the mean range cash price for: MRI was $3,793 ($464-$6,215); ultrasound was $767 ($136-$1,391); cardiac surgery was $236,125 ($72,250-$349,782); joint replacement was $46,008 ($22,170-$71,985); and childbirth was $19,568 ($7314-$29,068).

"There is wide variation in prices among hospitals for identical services," the authors wrote. "These price differences suggest the potential for significant cost savings for patients."

CMS Drops the Compliance Hammer

Of course, this failure of compliance has hardly gone unnoticed by the regulators. On July 9, President Biden issued an Executive Order (EO) calling on the Department of Justice and other federal government agencies to vigorously enforce the antitrust laws across all markets, including health care. As part of the effort to promote more active competition in health care, the EO instructs the Department of Health and Human Services to support price transparency.

Less than two weeks later, CMS finalized a proposal to increase penalties for price transparency. Published as part of the agency's proposed 2022 Outpatient Prospective Payment System (OPPS) proposed rule released in mid-July, the proposal would increase maximum civil monetary penalties to:

- $300 per day for smaller hospitals with a bed count of 30 or less; and
- $10 **per bed** per day for hospitals with bed counts above 30, subject to a maximum of $5,500 per day.

Under the proposal, the **minimum** total penalty of each hospital found to be in compliance for a full year would be $109,500, and the maximum total penalty would be $2,007,500.

Takeaway

There are two basic reasons why hospitals aren't complying with price transparency. The first is the calculation that the costs of compliance outstrip the potential penalties. The newly proposed fine increases should take that option off the table. "With today's proposed rule, we are simply showing hospitals through stiffer penalties: concealing the costs of services and procedures will not be tolerated by this administration," CMS Administrator Chiquita Brooks-LaSure said in a statement.

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However, the second reason for noncompliance is that hospitals want to comply but haven't yet been able to do so. Accordingly, CMS is seeking comments on other potential avenues for scaling the monetary penalties, including factoring in the hospital's reasons for noncompliance and the severity of the situation. To ease the compliance burden, the agency is also seeking comments on best practices for online price estimator tools that hospitals can use in lieu of posting standard charges for 300 shoppable services.

LABS IN COURT

University of Miami Settles Lab Testing False Claim Charges for $22 Million

The University of Miami's sports teams proudly refer to their school as "The U." But to the whistleblowers who brought the original lawsuit against the University at the center of this settlement, "The U" stood for "unnecessary," as in medically unnecessary lab tests billed to Medicare by the University's lab and off campus hospital-based facilities. Rather than risk a trial, the University has agreed to fork over $22 million to settles a trio of whistleblower lawsuits filed in 2013 and 2014, alleging that the University and its affiliates:

- Converted multiple physician offices to Off-Campus Hospital Facilities so it could bill Medicare for higher rates and without providing beneficiaries the required notice;
- Used its electronic ordering system to automatically prompt physicians to order multiple medically unnecessary tests for kidney transplant patients
- Submitted inflated claims for reimbursement for pre-transplant lab testing done by an affiliate that the affiliate should have billed for directly and then using the Medicare payments to pay the affiliate kickbacks for referring surgical patients.

Takeaway

The first thing to take away from this settlement and situation is recognition of the importance of ensuring compliance with the Off-Campus billing of Medicare patients notice requirements. Such

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requirements count as conditions of payment and not complying with them can turn the claim into a false claim. The other moral of the story is that "standing" orders remain highly risky and are allowed only when strictly tailored to each patient's individual circumstances and needs.

Risky Business: Illumina Rolls the Dice by Acquiring Grail Without Regulatory Approval

Deliberate defiance of government regulators takes gumption, even when those regulators are located an ocean away. However, that's the strategy that Illumina's corporate leadership has chosen in announcing that the company has completed its acquisition of Grail even though the European Union (EU) has not and may not approve the deal due to its anti-competitive effects.

The Illumina Acquisition of Grail

On Sept. 21, 2020, Illumina announced that it had signed a definitive agreement to acquire Grail, the liquid biopsy firm it spun off in 2016 and which had announced its own plans to go public just a week earlier. **The price:** $3.5 billion in cash and $4.5 billion in shares of Illumina common stock. Under the acquisition agreement, which was approved by each company's board of directors, Grail shareholders, who include Bill Gates and Jeff Bezos, would also get payments of 2.5 percent off the first $1 billion of Grail-related revenues and 9 percent off revenues above $1 billion per year over 12 years.

The deal enables Illumina to expand its position in the early cancer diagnostics market. Grail just launched a highly touted blood-based screening test called Galleri that uses methylation sequencing for ultra-early detection of over 50 different types of cancers. Illumina's president and CEO described Galleri as being "among the most promising new tools in the fight against cancer," and said that the acquisition would help Illumina "transform cancer care using genomics and our NGS platform." Illumina, which currently owns 12 percent of its former spinoff, is also the supplier of the sequencers that Grail uses for performing its genomic tests. Bringing the two companies back together would put the testing and sequencing under one roof.

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The Reaction to the Acquisition

Even so, reaction to the announced deal was decidedly lukewarm. Investors were spooked by the high purchase price and the apparent lack of fit. After rumors of the buyback drove Illumina share prices down about 11 percent, announcement of the actual deal caused another decline of 4.5 percent.

Investors weren't the only skeptics. Regulators, too, had their doubts. The U.S. Federal Trade Commission (FTC) expressed concerns over the new cancer genomics powerhouse's potential to dampen competition. But the FTC backed off by securing federal court approval to postpone legal action to block the deal pending resolution of the situation in Europe. Of course, the very fact there even was a situation in Europe was the big story.

That situation began in April when the European Commission's Directorate-General of Competition announced that it planned to review the deal under its controversial new guidance that enables the Commission to demand notification of a deal even when no such notification is required by the member states. "The combined [Illumina/Grail] entity "could restrict access to or increase prices of next-generation sequencers and reagents to the detriment of Grail's rivals active in genomic cancer tests following the transaction," according to a Commission statement.

To make things even tougher for Illumina, the EU delayed its investigation making it all but impossible for the deal to get regulatory approval by the closing deadline stipulated in the acquisition contract and leaving Illumina responsible to pay Grail a $300 million termination fee.

Illumina Hurls Down the Gauntlet

Illumina, which has challenged the EU's jurisdiction over what it contends is a purely U.S. acquisition, has decided not to allow the Commission to "run out the clock." On August 18, the company announced that it has gone ahead and acquired Grail, which it will hold as a wholly-owned company that will operate independently while the EU reviews the deal. "The stakes here are high because, simply put, this deal saves lives," Illumina CEO Francis deSouza told investors.

Takeaway

Mr. deSouza couldn't be more right. The stakes are indeed high. Illumina expects the Commission to respond to the deal's closing by trying to impose a fine of 10 percent of the company's consolidated annual turnover. If the EU subsequently rejects the deal, Illumina will likely go to court to challenge the decision. And even if Illumina makes it through the EU and courts, the FTC hasn't approved the deal and will be free to make its own decision. The end game of all this is that Illumina may have to wind down the acquisition and end up wasting massive investments of money, time and energy.

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COVID-19: CMS Couldn't Verify Hospital Safety During COVID and Won't Be Able to Do So in Next Pandemic

CMS was unable to determine whether hospitals were maintaining quality and safety standards during the COVID-19 crisis. And unless changes are made to its regulatory powers, it won't be able to make that determination during the next pandemic, either. At least, those are the findings of a new OIG report. Here's a quick briefing on what the OIG said.

Current CMS Oversight System

Among other things, CMS is charged with ensuring that the roughly 4,700 hospitals certified to participate in Medicare and Medicaid meet specified quality and safety standards. To carry out this oversight mandate, the agency relies on surveys carried out by state survey agencies; in some cases, hospitals are deemed to be certified when they're accredited by a recognized private organization.

In February 2019, CMS called on hospitals of the critical need to update their emergency preparedness plans to prepare for emerging infectious diseases. However, because accreditation organizations typically follow three-year quality and safety inspection cycles, the agency couldn't make an immediate determination to ensure that all accredited hospitals, i.e., hospitals not inspected by state surveyors, were in compliance and wouldn't be in a position to do so until 2022.

COVID-19 Exposes System's Weakness

After COVID-19 emerged in the U.S., CMS requested, but couldn't require, accreditation organizations to perform special targeted infection control surveys to prepare for COVID-19 patients. Because it was just a request, accreditation organizations performed no such special surveys; it was thus left to the state survey agencies to verify "compliance." But as of Aug. 17, 2020, only 13 percent of accredited hospitals were surveyed by state survey agencies. And because of CMS' limited regulatory powers, there were 13 states in which not a single accredited hospital was surveyed.

As a result of these limitations, according to the OIG report, CMS couldn't ensure that accredited hospitals would continue to provide quality care and operate safely during the COVID-19 emergency; and as long as these regulatory hurdles remain in place, the agency won't be capable of monitoring accredited hospital compliance with quality and safety requirements the next time a pandemic hits the U.S. "CMS' authority is not sufficient for it to fulfill its responsibility to ensure that accredited hospitals would maintain quality and safety during an emerging infectious disease emergency," the report concludes.

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Recommendations

The OIG report recommended that CMS make regulatory changes to allow it to require accreditation organizations to perform special surveys of hospitals CMS selects:

- After it issues new substantive participation requirements or guidance that it determines warrant additional validation to ensure timely compliance; and
- During a public health emergency to address the risks the emergency presents.

Billing and Coding: Medicare to Reimburse 6 New CLIA-Waived Tests, Starting Oct. 1

The FDA recently approved a half a dozen assays as CLIA-waived tests that Medicare will reimburse when properly billed and coded by CLIA-certified labs. On Aug. 6, CMS sent out coding instructions to Medicare Administrative Contractors. Here's a rundown of the information that your lab's billing staff needs to know.

Billing of New CLIA-Waived Tests

CLIA regulations require labs to be appropriately certified for each test they perform. CMS edits lab claims at the CLIA certificate level to ensure that Medicare pays only for lab tests categorized as waived complexity under CLIA in facilities with a CLIA certificate of waiver. The edits ensure that payments for the particular test don't go through if the lab doesn't have the proper CLIA certificate of waiver.

QW Modifier Tests: Starting Oct. 1, 2021, Medicare will reimburse the CPT codes for the following new tests, 80305, provided that they have the modifier "QW" to ensure they're recognized as a waived test:

CPT Code	Effective Date	Description
80305QW	Oct. 9, 2020	American Screening LLC Discover Panel Dip Card Tests MOR 2000
80305QW	Oct. 9, 2020	American Screening LLC OneScreen Plus Panel Dip Card Tests MOR300

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CPT Code	Effective Date	Description
80305QW	Oct. 9, 2020	American Screening LLC OneScreen Plus Panel Dip Card Tests MOR2000
80305QW	Oct. 9, 2020	American Screening LLC Reveal Panel Dip Card Tests MOR300
80305QW	May 3, 2021	Lendas UAB EXPLORO Highly Sensitive THC test
80305QW	May 5, 2021	Clinical Reference Laboratory CRLStat Multi-Drug Urine Test Cup

■ Kickbacks: OIG Sheds Light on When Price Reductions Must Meet Discounts Safe Harbor, *from page 1*

The Legal Challenge

The AKS makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, the referral of an item or service reimbursable under Medicare or another federal health care program. Discounts and price reductions are a form of illegal "remuneration" the law prohibits.

However, an AKS "safe harbor" allows for "discounts," i.e., reductions in the amount a buyer is charged for an item or service based on an arm's-length transaction, provided that the arrangement meets strict conditions. Among other things:

- The seller must make the discount at the time of the sale of the item or service;
- If the discount is in the form of a rebate, the rebate terms must be fixed and disclosed by the seller in writing to the buyer at the time of the initial sale; and
- The buyer must provide, "upon request by the Secretary or a State agency" an "invoice, coupon or statement" from the seller that "fully and accurately" reports the discount.

The Proposed Arrangement

The arrangement at the center of Opinion 21-06 involves a DME manufacturer that sells its spinal implants and devices via a traditional distribution system, including deployment of sales representatives and/or distributors ("Intermediaries"). The Intermediaries typically perform extra services before, during and after surgeries in which the manufacturer's

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products are used, e.g., with regard to training. The manufacturer pays the Intermediaries for performing these services and factors the compensation into the prices it charges hospitals for the products.

But under the proposed arrangement, the hospitals would buy the product directly from the manufacturer with no Intermediaries involvement. As part of the deal, the hospitals would perform the services normally carried out by the Intermediaries themselves. So, the manufacturer wanted to know if it would be okay to reduce the price of the products to account for the value of these services.

What the OIG Said

The OIG gave the all-clear. This wasn't really a discount, the agency reasoned. "Rather than bestowing something of value, the reduction in price simply would reflect the reduction in services the Participating Hospital would be purchasing." And to the extent that the price reduction doesn't constitute remuneration, the arrangement wouldn't violate the AKS, the OIG concluded.

Takeaway

The significance of this Opinion is the OIG's approach of placing substance over form. Specifically, the agency considered the entirety of the arrangement; the mere fact that the hospitals got a reduced price wasn't enough to make the arrangement a "discount." And that's good news because if an arrangement isn't a "discount," you don't have to navigate the tricky and cumbersome discounts safe harbor.

Of course, the substance-over-form approach can also cut the other way. Thus, arrangements may constitute discounts even if they don't provide a price reduction, including situations where labs offer labeling and other forms of service to physicians for free.

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