Report on
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Weekly News and Compliance Strategies on Federal Regulations, Enforcement Actions and Audits

Contents

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Gift Cards Are at Heart of FCA Settlement for $13.75M; OIG Approved Similar Arrangement

Exact Sciences Corp. (ESC) and its subsidiary, Exact Sciences Laboratories LLC (ESL), which administers Cologuard, a colon cancer screening test, agreed to pay $13.75 million to settle false claims allegations that certain patient gift cards were kickbacks.[1] The settlement came down seven months after the HHS Office of Inspector General (OIG) posted a favorable advisory opinion about the same kind of arrangement.[2]

The False Claims Act (FCA) lawsuit was filed by a patient turned whistleblower. According to the settlement with the U.S. Department of Justice (DOJ), the whistleblower alleged that Exact Sciences offered some patients who had been prescribed Cologuard prepaid Visa gift cards or Super Certificates to return a stool sample and complete the test in violation of the Anti-Kickback Statute (AKS) from April 1, 2015, to Oct. 31, 2020. The gift cards and Super Certificates were worth between $10 and $75, and Exact Sciences billed Medicare and TRICARE for the Cologuard tests.

"It sends a strong message that you can't use cash or cash equivalents to buy government business," said attorney Marlan Wilbanks, who represents the whistleblower.

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DOJ: New Safe Harbor Offers Way Out of Prosecution for M&A-Related Misconduct, With Caveats

Companies that self-disclose criminal misconduct related to mergers and acquisitions now have an escape hatch from criminal prosecution under a U.S. Department of Justice (DOJ) policy announced Oct. 4.[1]

To qualify for the new safe harbor, companies are required to voluntarily self-disclose to DOJ any criminal wrongdoing they uncover at an acquired entity within six months of the closing date—"whether the misconduct was discovered pre- or post-acquisition," Deputy Attorney General Lisa Monaco said at the Compliance and Ethics Institute sponsored by the Society of Corporate Compliance and Ethics. Companies have one year from the closing date to remediate the misconduct.

"The carrot is a promise of declination—no criminal charges against the company," said attorney Matthew Krueger, with Foley & Lardner LLP. The safe harbor is offered to the company—the acquiring company and the acquired company, unless aggravating factors exist. "There are caveats," such as the entity fully cooperating, which DOJ views as "disclosure of all facts and all responsible individuals," he explained. In other words, people from the acquired company who are responsible for the wrongdoing "may still face criminal exposure by virtue of this policy. This fits with the department's overall goal of holding individuals accountable by giving more incentives to disclose culpable individuals," which Monaco reiterated in a 2021 memo.[2]

Monaco explained that DOJ is emphasizing "timely compliance-related due diligence and integration. Compliance must have a prominent seat at the deal table if an acquiring company wishes to effectively de-risk a transaction. By contrast, if your company does not perform effective due diligence or self-disclose misconduct at an acquired entity, it will be subject to full successor liability for that misconduct under the law."

continued

Krueger said the safe harbor is part of a broader push by DOJ to make the incentives for a robust compliance program clearer and more enticing. Other moves along these lines include the corporate enforcement policy, announced in January 2023, which spells out the rewards for companies that self-disclose their involvement in possible criminal wrongdoing and cooperate with DOJ.[3] The cooperation credit includes a penalty that's not more than 50% of the low end of the Sentencing Guidelines range for companies without aggravating factors. Monaco also unveiled a pilot in March that rewards corporations for compensation clawbacks from culpable individuals as part of corporate criminal resolutions.

As she said in the speech, "If you've been paying attention to the policies we've implemented over the past two years, you've probably noticed that I talk a lot about empowering general counsels and compliance officers—to make the case in the board room and the c-suite for investments in compliance—and to make the case that investing in strong compliance programs is good for business."

The message from the safe harbor is the importance of due diligence, added Krueger, former U.S. Attorney for the Eastern District of Wisconsin. That includes vetting the target's compliance program. "If it just seems like a compliance program on paper, that's a red flag," he said. Same goes for a dearth of hotline calls and investigations. But it's encouraging if the company has policies and procedures, investigates hotline calls and follows up on corrective actions. "That gives you more comfort about the entity being acquired," Krueger said.

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DOJ Is Adding More Prosecutors

Monaco also talked more broadly about the expansion and innovation of corporate enforcement. "More and more of our corporate resolutions implicate our national security," she said. "To meet this moment, we are adding more than 25 new corporate crime prosecutors in the National Security Division, including the division's first-ever Chief Counsel for Corporate Enforcement." The criminal division also increased the number of prosecutors in its Bank Integrity Unit by 40%.

There also are new tools to punish and deter. This year DOJ for the first time required divestiture of lines of business and tailored compensation and compliance requirements as part of corporate criminal resolutions. For example, the antitrust division's deferred prosecution agreements with two pharmaceutical companies—Teva Pharmaceuticals USA Inc. and Glenmark Pharmaceuticals Inc.—included monetary penalties and divestiture of "a widely used cholesterol medicine that was a core part of the companies' price-fixing conspiracy," she explained.[4]

Compliance Is Not a Cost Center

DOJ also is very focused on compensation's effect on employee behavior. That's why the criminal division earlier this year created a pilot program that adds a compensation dimension to criminal resolutions. Every corporate resolution with the DOJ criminal division will require the corporation to have "compliance-promoting criteria within its compensation and bonus system," she said when it was announced.

"The pilot program also rewards companies that claw back or withhold incentive compensation from executives responsible for misconduct—or attempt to do so in good faith," Monaco elaborated at the Compliance and Ethics Institute. "For every dollar that a company claws back or withholds from an employee who engaged in misconduct—or a supervisor that knew of or turned a blind eye to it—the Department will deduct a dollar from the otherwise applicable penalty that the resolving company would pay."

She emphasized that companies shouldn't be viewing compliance as a cost center. "Good corporate governance and effective compliance programs can shield companies from enormous financial risks and penalties."

Looking ahead, she said DOJ plans to apply its corporate enforcement principles in civil and criminal enforcement, especially when it comes to cybersecurity, tech and national security. There will be more to come on individual accountability, incentivizing compliance, self-disclosure and cooperation and penalizing "repeat bad actors."

An unanswered question is how these developments will affect False Claims Act (FCA) enforcement, which is the preeminent enforcement threat to health care organizations, Krueger said. "As Monaco described the new safe harbor, it doesn't necessarily apply to False Claims Act enforcement,

which is a civil statute, because Monaco described incentives relevant to criminal enforcement, such as declination of charges. But she also is asking the department broadly to adopt similar programs, so I'm curious to see whether there will be similar revisions to the False Claims Act disclosure process." For example, is DOJ willing to promise a specific reduction in damage multiples if companies self-disclose FCA issues after a merger or acquisition? He will be watching to see if that materializes in the part of the Justice Manual that addresses voluntary self-disclosure in the FCA context.

Contact Krueger at mkrueger@foley.com. ✧

Endnotes

1. Lisa O. Monaco, "Deputy Attorney General Lisa O. Monaco Announces New Safe Harbor Policy for Voluntary Self-Disclosures Made in Connection with Mergers and Acquisitions," U.S. Department of Justice, Office of Public Affairs, speech, October 4, 2023, https://bit.ly/3thbIxz.
2. U.S. Department of Justice, "Corporate Crime Advisory Group and Initial Revisions to Corporate Criminal Enforcement Policies," memorandum, October 28, 2021, https://bit.ly/3GQ9Xtp.
3. Nina Youngstrom, "In New Policy, DOJ Spells Out Rewards for Self-Disclosure, Reinforces Compliance Programs," *Report on Medicare Compliance* 32, no. 3 (January 23, 2023), https://bit.ly/3ZyvI9Z.
4. U.S. Department of Justice, Office of Public Affairs, "Major Generic Drug Companies to Pay Over Quarter of a Billion Dollars to Resolve Price-Fixing Charges and Divest Key Drug at the Center of Their Conspiracy," news release, August 21, 2023, https://bit.ly/3PBP6iE.

GHI Pays $32.5M to Settle FCA Case; Gaming of 14-Day Rule Alleged

In a case about Medicare's rule on billing for certain lab tests within 14 days of a patient's discharge from the hospital, Genomic Health Inc. (GHI) has agreed to pay $32.5 million to settle false claims allegations, the U.S. Department of Justice (DOJ) said Oct. 2.[1] The test in question here—Oncotype DX—is a proprietary genetic test used to diagnose and treat breast, prostate and colon cancer patients.

The case, which was set in motion by two separate whistleblower lawsuits, centers on CMS's rule on billing for tests performed by third-party laboratories when patients are in the hospital. The so-called 14-day rule stipulates that third-party labs must bill the hospital if the physician orders the test during the patient's stay or within 14 days of discharge. After that, Medicare will pay separately for tests. "When a hospital must reimburse a third-party laboratory for a test ordered less than 14 days from discharge, that reimbursement has the effect of diminishing the value of the fixed DRG payment the hospital received for that patient," according to the 2016 whistleblower complaint filed by Samuel Caughron, M.D., who was laboratory medical director of Shawnee Mission Medical Center in Kansas and director of the Molecular Lab at MAWD Pathology Group in Missouri at the time the complaint was filed.[2]

Caughron alleged he started to suspect that some labs and/or hospitals delayed or rescheduled tests or held specimens to take advantage of the 14-day rule, "to the possible detriment of Medicare patients" and with "the certain consequence of causing" Medicare to absorb the costs.

The whistleblower recorded calls with two GHI representatives about the 14-day rule. In one call, a GHI sales manager allegedly told Caughron that because most hospitals say they don't want to pay the bills for Oncotype DX, "what we do is we cancel the order…we notify the treating physician that it was canceled because it was under 14 days, and, and, you know, if, if after 15 days they want to reorder, then they can reorder and we will bill Medicare."

Because GHI enabled hospitals to keep more of the DRG payments for patients who had Oncotype DX testing, GHI provided a financial benefit to "induce" hospitals to order more Oncotype DX tests paid for by Medicare, the complaint alleged. "Meanwhile, Medicare-enrolled patients wait for their test results and suffer because of that wait."

GHI, which was acquired by Exact Sciences Corp. in November 2019, didn't admit liability in the settlement. Morry Smulevitz, senior vice president for corporate affairs at Exact Sciences, said, "We were pleased to recently resolve the matter related to Medicare's 14-Day Rule that resulted from legacy policies at GHI prior to its 2019 acquisition by Exact Sciences."

Lawyer: Easier to Monitor Bright-Line Rules

Cases tend to be more challenging for providers when there's a bright-line Medicare rule like the 14-day rule, said attorney John Kelly, with Barnes & Thornburg LLP in Washington, D.C. "When a rule is very date-specific, it makes it more challenging to argue that a violation was due to it being vague or simply an unintended technical violation."

But it's also easier to monitor for outliers, he said. If there were "an uptick in the number of tests cancelled and re-ordered, that's a red flag." It's also important to have a policy on the provider side to follow up and ensure the tests are performed, preferably in 14 days, Kelly said. If not, "you get an explanation."

According to the settlement, from 2008 through Feb. 29, 2020, "GHI cancelled, delayed, held or otherwise did not process orders for tests that were subject to the DOS [date of service] Rule and submitted claims for reimbursement to the Medicare Program with a date of service that resulted in direct reimbursement to GHI. This caused the Medicare Program to incur additional costs beyond what it would have otherwise paid."[3]

Similar allegations apply to outpatients for 2008 through 2017. "During the period January 1, 2007 through December 31, 2018, GHI knowingly and willfully paid remuneration to hospitals by deliberately failing to collect payments from those hospitals for tests performed by GHI for the hospital's in-patients and outpatients when the tests were ordered within 14 days following the patient's discharge from the hospital. As a result, GHI violated the Anti-Kickback Statute," the government alleged.

Contact Kelly at jkelly@btlaw.com. ✧

Endnotes

1. U.S. Department of Justice, Office of Public Affairs, "Genomic Health Inc. Agrees to Pay $32.5 Million to Resolve Allegations Relating to the Submission of False Claims for Genetic Cancer Screening Tests," news release, October 2, 2023, https://bit.ly/3tkjmHz.
2. Complaint, United States ex rel. Caughron v. Genomic Health, Inc., No. 16-CV-04038-LDH-RML (E.D. N.Y.), https://bit.ly/3Q2katy.
3. Settlement agreement, United States ex rel. Caughron v. Genomic Health, Inc., No. 16-CV-4038 (E.D. N.Y.), https://bit.ly/3PI2yBQ.

Compliance Liaisons, Required for SNFs, Can Help Outreach Everywhere

Compliance liaisons—now required for larger skilled nursing facility (SNF) organizations—can help extend the reach and engagement of a compliance program, and organizations not required to have compliance liaisons might want to consider adding them.

Joseph Zielinski, attorney and director of legal affairs at CarDon & Associates Inc.—a senior living company that operates 20 senior centers in central and southern Indiana—said that adding compliance liaisons can help bridge gaps between operations and compliance and increase engagement with individual departments and offsite facilities.

Organizations are free to design the program that fits their corporate structure best, Zielinski said Sept. 7 at a webinar sponsored by the Health Care Compliance Association.[1] "There is no one-size-fits-all program," he said. "You need to be aware of what your individual program needs to have and what the risks to your program are."

Compliance liaisons function as an intermediary between the compliance program and the operation stakeholders throughout the organization. While some types of organizations have chosen a compliance liaison model to promote compliance program effectiveness, SNF operators with five or more facilities are required to have compliance liaisons under Phase III of CMS's updated Requirements of Participation for Long-Term Care Facilities, updated in 2016.[2]

The "compliance liaison" isn't a defined term, Zielinski said. Although there aren't prescriptive job responsibilities in the rule, "[a]t a minimum, these liaisons should be responsible for assisting the compliance officer with his or her duties under the operating organization's program at their individual facilities."[3] SNF operators also must designate a compliance officer at the corporate level.

Outside the SNF world, organizations might want to add a compliance liaison, Zielinski said. Creating a compliance liaison role within an organization can help connect compliance to the field and operations in general, he said, allowing for engagement that might not otherwise be possible.

"Also, compliance liaisons can be helpful because they can bring a different perspective. They're not, per se, coming from that compliance background. This is an operational person who has been tasked with compliance functions. So how they approach compliance is going to be different," he said.

Potential Responsibilities for Liaisons

The compliance liaison functions as "the boots on the ground within the facility," Zielinksi said. The liaison's responsibilities may include:

- Serving as the in-person resource for compliance-related issues and questions
- Representing the compliance program in facility-level meetings
- Coordinating with the Quality Assurance and Performance Improvement (QAPI) committee on the compliance program
- Encouraging transparency and reporting
- Helping with in-person portions of investigations
- Performing monitoring of higher-risk functions in accordance with the work plan and/or auditing and monitoring plan
- Incorporating the facility and hazard vulnerability assessments into the work plan
- Conducting in-person compliance training

"They should help to distribute information, they're going to help manage records, and they're going to manage that meeting cadence at the facility level," Zielinski said. "They may be involved in risk planning. They may have a better idea of what the risks are to their building—and we know when you're doing a risk assessment, you want it to be as customized to your facility and organization as you can make it."

The CMS rule provides flexibility to organizations on how the role should be structured and tailored, Zielinski said. However, he said organizations should consider roles that already spend time working in compliance or a related field, such as auditing, investigations, quality or regulatory issues.

The right person for the role would be approachable and a good communicator who is able to build a rapport and engage staff buy-in, Zielinski said. "You want to make sure that they've got the right soft skills—that this person is approachable, that they know how to connect and build rapport with different staff."

In addition, Zielinski pointed out, "time is going to be a very key requirement—you're going to have to think about the fact that the person who you select for this probably already has a full-time job and a work load, and you're now going to be adding onto that work load."

Good Fit for Role?

When selecting a compliance liaison, there are certain positions that may be well-suited, Zielinski said. These include:

- **Nursing home administrator/executive director.** This role already reports directly to the board,

attends the necessary meetings and has the appropriate authority, Zielinski said.

- **Assistant administrator.** This is a good option in larger facilities that have an assistant administrator, Zielinski said. The role has access to the board, and the individual has an enterprise and holistic view of the facility, attends the necessary meetings, is familiar with the facility policies and procedures and has the appropriate influence in the community, he said. One possible downside of this role is job turnover, Zielinski said. "You may not have people staying in this role long—they may be looking to advance to that administrator role or some other kind of executive position."
- **Director of nursing.** "This is a good option if your community is one that needs more clinical help, since they're going to be knowledgeable about your facility's clinical practices, survey challenges and care issues," Zielinski said. "They're going to have experience with audits, and they're going to have clinical knowledge that they may be able to fill in that you wouldn't have in some of these other administrative roles." However, directors of nursing might not have time to take on more responsibilities, he said.
- **Staff development coordinator.** This could be a good option because staff development coordinators focus on training and education and already have the right skill set and soft skills to engage and interact with staff, Zielinski said. However, he noted that staff development coordinators don't have an enterprise view of the facility or direct access to the board.
- **Human resources.** This may not be a leadership role at the facility level or be the right person for the position even though people in human resources are used to handling investigations, making reports and having access to the necessary systems, Zielinski said.
- **Minimum data set coordinator.** This role likely is coordinating with multiple departments to gather needed information but likely is not in a position of leadership, Zielinski said. Still, this role could be considered if the facility has concerns about billing or coding

Coordinating Across Facilities

As organizations select compliance liaisons, they face several challenges, Zielinski said. For example, the organization must decide whether to choose the same title at each facility—e.g., the nursing home administrator across the board—or to appoint different titles in each facility, depending on expertise, interest, personality and facility needs.

In addition, compliance liaisons will need to be educated on what to do if and when their operations' responsibilities appear to collide with their compliance responsibilities, Zielinski said.

Finally, the organization must decide whether the additional duties of compliance liaisons warrant additional compensation.

Because the individual stepping into the role already has a full-time job, the organization may need to make some changes to their duties, Zielinski said. "Work balance and support is going to be key. So, how are you supporting the individual in this role? What kind of resources are you providing to this individual?"

The organization should have a job description written clearly so that both compliance liaisons and the organization understand the roles and responsibilities, Zielinski said. In addition, the organization should ensure the role has the necessary resources to perform the duties and should ensure clear communication about the role and its authority as an extension of the compliance program, he said. The role should be part of the person's annual evaluation, as recommended by CMS, he said. ✧

Endnotes

1. Joseph Zielinski, "Compliance Liaisons – Who and Why," Health Care Compliance Association, webinar, September 7, 2023, https://bit.ly/3LRuSk9.
2. 42 C.F.R. §483.85.
3. Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities, 80 Fed. Reg. 42,220, (July 16, 2015), https://bit.ly/3LBRg0L.

Information Blocking Enforcement May Ease EHR Problems, Lawyer Says

The HHS Office of Inspector General's (OIG) enforcement rule on information blocking, which took effect Sept. 1, may be a vehicle for hospitals and their vendors to access data when electronic health record (EHR) vendors don't make it easy, an attorney said.[1]

Some EHR vendors ask other hospital vendors to jump through hoops to get data they need for billing, quality improvement and other activities, according to attorney Sean Sullivan, with Alston & Bird LLP in Atlanta, Georgia. He said the hoops include separate contracts, licensing fees, long waiting periods and requirements that other vendors use separate platforms instead of "directly accessing the hospital's native EHR system." What's ironic is the vendors are business associates of hospitals under HIPAA and have business associate agreements, which means the hospitals have already paved the way for the vendors to access the data, Sullivan said.

If the EHR vendors interfere with the access, use and exchange of electronic health information (EHI), hospitals could report them to OIG under the information blocking rule, he said. "It remains to be seen if OIG will go after this type of activity, but I think it falls right within the wheelhouse of their enforcement priorities."

The information blocking regulation, which took effect April 5, 2021, is intended to ensure patients, providers and others have unfettered, timely access

to EHI. According to the final regulation from the HHS Office of the National Coordinator for Health Information Technology (ONC), any action or inaction that knowingly interferes with the access, exchange or use of electronic protected health information may lead to penalties or "disincentives."[2] Information blocking by "actors" (providers, health information networks/health information exchanges and developers of certified health information technology) is prohibited unless a practice is required by law or falls into one of eight exceptions (e.g., sharing the information would cause patient harm). As of Oct. 6, 2022, the information blocking rule applies to the entire designated record set.

Although OIG's enforcement rule applies only to health information networks/health information exchanges and developers of certified health information technology, a separate enforcement rule is coming for providers.

Look to Infeasibility Exception

Here's an example of the supposed EHR interference with other vendors' access to EHI that was published in comments to the proposed version of OIG's enforcement rule: "I work for a company that offers innovative software to hospital systems to help them provide better patient care. Access to EMR data is integral for providing this operational support. EMR vendors have a variety of systems that store and serve data that we currently use. Several of these systems are available to EMR hospital customers, but are restricted behind proprietary schemas from third-party vendors. As one explicit example, Epic Systems has a Clarity database that stores clinical and operational data generated during the clinical encounter. The EMR vendor restricted access to these data stores is true even in the case where a hospital system EMR customer requests the third-party vendor's help. While third-party vendors can access these systems technically today, it is often in violation of hospital contracts signed with the EMR vendors. As the information blocking rules transition from the narrow USCDI standard to the broader 'diagnostic record set,' there is a real risk that EMR vendors will aggressively restrict third-party access to data stores, databases, and end-points that store vast amount of non-USCDI data that will fall under the Cures Act's ultimate definition of Electronic Health Information. We urge the OIG to consider monitoring and penalizing any EMR vendor moves to restrict access to these non-USCDI data systems during the 24-month transition period."[3]

In light of the enforcement rule, Sullivan said, "EHR developers need to get up to speed on those rules and ensure none of their activities, procedures or contracts interfere with access to those records." There's also an opening in the proposed modification to one of the information blocking rule exceptions. Actors are protected when they deny access, exchange or use of EHI due to the infeasibility of the situation, such as technology limitations or uncontrollable events. In an April 18 proposed rule on Health Data, Technology and Interoperability, ONC recognized the potential problem with business associates like EHR vendors inhibiting access to EHI, so it proposed adding a new provision to the infeasibility exception, Sullivan said.[4]

ONC affirmed that an actor like an EHR developer may be information blocking when it interferes with a request to modify EHI, Sullivan explained, "when the request is from a health care provider requesting (directly, or through another business associate of the health care provider) such modification use from an actor that is its business associate…" according to the proposed rule.

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Endnotes

1. Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; Office of Inspector General's Civil Money Penalty Rules, 88 Fed. Reg. 42,820 (July 3, 2023), https://bit.ly/3rAbbWW.
2. 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, 85 Fed. Reg. 25,642 (May 1, 2020), https://bit.ly/32vJ6RI.
3. Inspector General Office, Health and Human Services Department, "Comment on FR Doc # 2020-08451," Regulations.gov, comment ID: HHSIG-2020-0001-0027, July 1, 2020, https://bit.ly/3PJl5xo.
4. Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing, 88 Fed. Reg. 23,746 (April 18, 2023), https://bit.ly/46eC3Lm.

Patient Gift Cards Lead to FCA Settlement

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But OIG's advisory opinion makes it hard to draw conclusions about the case, said attorney Ramy Fayed, with Dentons US LLP in Washington, D.C. "It's a very interesting and perplexing situation," he said. "It's hard to tell exactly what happened that would lead to the confluence of a favorable advisory opinion and a multimillion-dollar settlement for arguably what appears to be the same conduct." Fayed noted that it's conceivable the safeguards described in the advisory opinion weren't in place at the time the whistleblower alleged the company was paying kickbacks. (It came out during litigation that Exact Sciences requested the advisory opinion, Wilbanks said.)

The whistleblower, retired Florida physician Niles Rosen, had alleged that a $75 Visa reward card offered to him and other Medicare beneficiaries as part of Exact Sciences' Patient Compliance Program was unlawful remuneration intended to induce their use of Cologuard. In 2018, "Medicare paid defendants more than $160 million for Cologuard tests while defendants were offering unlawful cash equivalent inducements directly to government beneficiaries," according to the complaint. The subsequent claims submitted to Medicare by Exact Sciences violated the FCA because they were "tainted," the complaint alleged.[3]

The seeds of the complaint were planted in 2017 when a gastroenterologist prescribed Cologuard for

Rosen, who is also the former medical director of the CMS National Correct Coding Initiative. Rosen, who was asymptomatic, received the test from Exact Sciences, but decided not to take it. About three months later, Exact Sciences allegedly sent Rosen a letter with the Visa reward card offer. According to the complaint, the letter stated that "Because your health is important, Exact Sciences Laboratories will send you a $75 Visa reward card for completing your Cologuard Test! In order to qualify for this special offer, your sample must be received at Exact Science Laboratories by Thursday, March 22, 2018." Rosen subsequently decided to take the Cologuard test because he wanted the reward card, the complaint alleged. After he submitted the specimen to the lab, Rosen got the reward card and used it to buy items unrelated to health care.

Rosen later visited the MyMedicare.gov website to confirm that ESL billed Medicare for his test and determined the defendants were paid $498.69. "Defendant ESL's claim to Medicare for Relator's Cologuard test is a representative sample of the thousands of such false claims submitted to government payers for the Cologuard lab test," the complaint alleged. Under the AKS, it's unlawful to knowingly pay remuneration to the beneficiary of a government program to induce them to complete Cologuard tests and the gift cards, which are cash equivalents, constitute unlawful remuneration, the complaint alleged. The whistleblower contends he wouldn't have picked Exact Sciences for the test or had the test without the $75.

DOJ didn't intervene in the whistleblower's complaint, which survived a motion to dismiss last year. "The settlement was reached on the eve of trial while a Motion to Exclude the Advisory Opinion was pending before the Court," according to a press release from the whistleblower's law firms.

OIG Is OK With Gift Cards Under CMP, AKS

The March 29 advisory opinion was good news for the requestor, which asked OIG about the fraud and abuse implications of a proposal to provide prepaid cards, such as a Visa or Mastercard gift card, worth $75 to encourage patients to return the requestor's sample collection kit associated with its colorectal cancer screening test. The requestor, which is the parent company writing on behalf of itself and its subsidiary lab, is paid $500 for the colorectal cancer screening test. Patients are offered the gift cards by letter if they haven't returned the sample collection kit after the requester contacted them twice.

The requestor certified there were certain safeguards, including only mailing gift cards to patients who return test kits by the deadline in the letter and limiting the gift cards to one per patient every 36 months.

OIG gave the gift-card proposal a green light under the civil monetary penalty for beneficiary inducements because it meets an exception to the definition of "remuneration" under an exception for preventive care. OIG also concluded the gift cards present a "minimal risk of fraud and abuse" under the AKS for several reasons.

For example, the proposed arrangement probably won't increase federal health care program costs because the U.S. Preventive Services Task Force recommends

CMS Transmittals and *Federal Register* Regulations, September 29-October 5

Transmittals

Pub. 100-04, Medicare Claims Processing

- Diagnosis Code Update for Add-on Payments for Blood Clotting Factor Administered to Hemophilia Inpatients, Trans. 12,290 (Oct. 5, 2023)
- Deleting Internet Only Manuals (IOM) Pub. 100-04, Chapter 4, Section 190, Payer Only Codes Utilized by Medicare, Trans. 12,284 (Oct. 5, 2023)
- Internet Only Manual Updates to Pub. 100-02 and 100-04 to Implement Consolidated Appropriations Act 2023 Changes for Skilled Nursing Facility (SNF), Trans. 12,283 (Oct. 5, 2023)

Pub. 100-20, One-Time Notification

- Requirements for a Provider Direct Mailing and Education & Outreach for Behavioral Health Initiatives, Trans. 12,285 (Oct. 5, 2023)
- Patient Driven Payment Model (PDPM) Corrections to Interrupted Stay Edits, Trans. 12,286 (Oct. 5, 2023)

Pub. 100-02, Medicare Benefit Policy

- Internet Only Manual Updates to Pub. 100-02 and 100-04 to Implement Consolidated Appropriations Act 2023 Changes for Skilled Nursing Facility (SNF), Trans. 12,283 (Oct. 5, 2023)

Federal Register

Final rule; corrections

- Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2024 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Rural Emergency Hospital and Physician-Owned Hospital Requirements; and Provider and Supplier Disclosure of Ownership; and Medicare Disproportionate Share Hospital (DSH) Payments: Counting Certain Days Associated With Section 1115 Demonstrations in the Medicaid Fraction; Correction, 88 Fed. Reg. 68,482 (Oct. 4, 2023)
- Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2024; Correction, 88 Fed. Reg. 68,486 (Oct. 4, 2023)
- Medicare Program; FY 2024 Inpatient Psychiatric Facilities Prospective Payment System-Rate Update; Correction, 88 Fed. Reg. 68,491 (Oct. 4, 2023)
- Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2024 and Updates to the IRF Quality Reporting Program; Correction, 88 Fed. Reg. 68,494 (Oct. 4, 2023)

Notice

- Medicare Program; Medicare Appeals; Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2024, 88 Fed. Reg. 67,297 (Sept. 29, 2023)

the test every one to three years for people between the ages of 45 and 75 and Medicare only covers it every 36 months. OIG also said the proposed arrangement would encourage patient compliance with the recommended screening test that CMS has said would benefit patients and Medicare. The safeguards cited by the requestors also would reduce the risk of fraud and abuse.

But "advisory opinions don't override the Anti-Kickback Statute," said Wilbanks, with Wilbanks & Gouinlock, LLP. He alleged that Exact Sciences "didn't put all the relevant facts in the request" and noted the gift cards were only offered to Medicare and Medicare Advantage patients, not Medicaid patients.

'You Get a Little Bit of Whiplash'

It bothers Fayed to see a false claims settlement after OIG signaled its comfort with the arrangement. Although false claims settlements are the province of the Department of Justice, "you would hope" an advisory opinion would "insulate the requestor of the advisory opinion from liability for an alleged Anti-Kickback Statute violation that can bootstrap into a False Claims Act violation," he said. When OIG finds a minimal risk of fraud and abuse, it's hard to prove a company acted with actual knowledge or in reckless disregard or deliberate indifference, which is necessary for crossing the threshold of the FCA, Fayed said. Then again, it's hard to be certain of the sequence of events and safeguards in place at the time of the covered conduct.

More generally, Fayed said gift cards may not be appropriate in all circumstances. "You need to have the right set of facts and understand the requirements or limitations of an applicable exception or safe harbor." Giving gift cards to patients under the preventive care exception to the beneficiary inducement law is seen as permissible.

He wouldn't read too much into the Exact Sciences situation. "It sends conflicting messages," Fayed said. On the one hand, OIG gave a favorable opinion, and on the other hand, there was a high-dollar settlement. "You get a little bit of whiplash." Does the settlement devalue the advisory opinion or "suggest this type of arrangement is a 50/50 roll of the dice, or should there be a more principled analysis of these types of arrangements?"

Morry Smulevitz, senior vice president for corporate affairs at Exact Sciences, said, "Federal regulations allow companies to offer incentives to encourage patients to complete preventive care services like Cologuard. In fact, the Department of Health and Human Services recently issued an Advisory Opinion stating that it would not seek sanctions for a gift card program for colorectal cancer screening tests. We are committed to ethical and lawful business practices, including our partnership with government healthcare programs, and have a long history of compliance and a record of enhancing the compliance practices of the companies that we acquire."

He noted that Exact Sciences "is not admitting any wrongdoing but is settling this matter to avoid the cost and distraction of litigation and to focus on its mission—helping to eradicate cancer."

Contact Wilbanks at mbw@wilbanksgouinlock.com and Fayed at ramy.fayed@dentons.com. ✧

Endnotes

1. Settlement Agreement, Rosen v. Exact Scis. Corp., 8:19-cv-1526-MSS-AAS (M.D. Fla. Mar. 7, 2023), https://bit.ly/48IHNyp.
2. U.S. Department of Health and Human Services, Office of Inspector General, "Re: OIG Advisory Opinion No. 23-03," memorandum, March 24, 2023, https://bit.ly/3rOJytg.
3. Complaint, Rosen v. Exact Scis. Corp., 8:19-cv-1526-MSS-AAS (M.D. Fla. April 12, 2021), https://bit.ly/3CmKiZe.

NEWS BRIEFS

◆ **CMS on Oct. 5 posted a new edition of its Medicare Provider Compliance Newsletter.**[1] This issue addresses comprehensive error rate testing of hospital outpatient services and recovery audit contractor reviews of hypoglossal nerve stimulation for obstructive sleep apnea.

◆ **The Cigna Group and its Medicare Advantage organizations (MAOs) have agreed to pay $37 million to settle false claims allegations they submitted false and invalid patient diagnosis codes to inflate payments they got for Medicare Advantage members, the U.S. Attorney's Office for the Southern District of New York said Sept. 30.**[2] "The Government's Complaint alleged that the invalid diagnosis codes were based solely on forms completed by vendors retained and paid by CIGNA to conduct in-home assessments of plan members," the U.S. attorney's office said. Providers—usually nurse practitioners—who did the home visits allegedly didn't provide or order diagnostic tests or imaging that would have been necessary to diagnose the conditions reported and in many cases Cigna didn't allow them to treat patients during the home visits. "The diagnoses at issue were not supported by the information documented on the forms completed by the vendors and were not reported to CIGNA by any other healthcare provider who saw the patient during the year in which the home visits occurred," the U.S. attorney's office alleged. As part of the settlement, Cigna entered into a five-year corporate integrity agreement with the HHS Office of Inspector General. The false claims lawsuit was set in motion by a whistleblower lawsuit in the Southern District of New York but was transferred to the Middle District of Tennessee.

Endnotes

1. Centers for Medicare and Medicaid Services, "Guidance to Address Billing Errors," *Medicare Compliance Provider Newsletter* 13, no. 1 (September 2023), https://bit.ly/3F9cuPX.
2. U.S. Department of Justice, U.S. Attorney's Office for the Southern District of New York, "United States Reaches $37 Million Settlement Of Fraud Lawsuit Against Cigna For Submitting False And Invalid Diagnosis Codes To Artificially Inflate Its Medicare Advantage Payments," news release, September 30, 2023, https://bit.ly/3tjsxI9.