Report on
MEDICARE COMPLIANCE

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

Contents

DOJ Certification Raises CCO 'Risk Profile'; Consider 'Your Own Due Diligence Checklist'

A compliance officer's certification that her organization was compliant with applicable laws and regulations as part of its false claims settlement with the Department of Justice (DOJ) has come back to bite her. The organization is considering a self-disclosure that implicates the certification, a cautionary tale for other compliance officers now that DOJ is expected to require chief compliance officers to sign certifications that their organization's compliance program is "reasonably designed and implemented to detect and prevent violations of the law" and functioning effectively in the resolution of corporate criminal cases. That language has already made an appearance in Glencore International A.G.'s May guilty plea to Foreign Corrupt Practices Act violations and in speeches by top DOJ officials.[1]

The new DOJ compliance certification "compounds the risk profile of a compliance officer," said former prosecutor Robert Trusiak, who represents the compliance officer involved in the possible self-disclosure. The conundrum for compliance officers is they are "one step removed" from settlement negotiations with DOJ but could face criminal penalties for failures in their compliance program because of their signature on that certification, he said.

"A hard job just got harder," said Trusiak, a former compliance officer. "It's time you undertake your own due diligence checklist to address your concerns." He said it should include having the board of directors sign off on the minutes of compliance committee meetings, keeping "mirror" documentation of higher-risk transactions, and determining where they stand under the company's directors & officers (D&O) liability insurance policy.

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DOJ Alleges Fresenius Clinics Did Unnecessary Procedures; Compliance Raised Concerns

The Department of Justice (DOJ) said July 13 it has intervened in a whistleblower complaint against Fresenius Vascular Care Inc. (FVC) alleging medically unnecessary procedures were performed on patients with end-stage renal disease (ESRD) at nine of its clinics in New York.[1] With or without referrals from nephrologists and dialysis clinics, the Fresenius vascular access centers (VACs) allegedly did fistulagrams and angioplasties and held contests with prizes for new patient referrals, according to the False Claims Act (FCA) complaint in intervention.[2] Although the compliance department warned against the allegedly medically unnecessary procedures, DOJ said they continued.

"It is traditional profits over care," alleged Jeanne Markey, an attorney for the whistleblowers, both nephrologists who referred patients to Fresenius VACs. John Pepe, a physician at Staten Island University Hospital, and Richard Sherman, professor Emeritus at Rutgers University Medical School, were not employed by Fresenius, Markey said. "Often, it's an insider who becomes aware of [alleged misconduct] but that was not the case."

continued

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Fresenius denied the allegations and will "vigorously defend the litigation," it said in a statement.

ESRD patients have dialysis three times a week, typically in an outpatient center, and Medicare requires an interdisciplinary team to monitor vascular access. If there's a potential obstruction that could prevent dialysis from effectively cleaning the blood, a nephrologist may refer the patient to a VAC. According to the complaint, Fresenius' alleged "scheme" centered on clinically timed evaluations (CTEs). They began with the first visit to a VAC for a fistulagram, which involves penetrating the patient's skin and blood vessels with a needle and catheter and using imaging to visualize blood flow. Depending on the extent of the blockage, the interventionalist (a physician) performs an angioplasty, which requires a catheter insertion and insertion of a balloon to expand a vessel and restore blood flow.

The process was repeated because Fresenius VACs (FVACs) scheduled subsequent CTEs without another referral from their treating physician and "without regard to clinical findings," the complaint alleged. And CTEs weren't actually evaluations; FVAC staff allegedly "knew with near certainty before the patient arrived" that they would perform a procedure. The FVACs "would then routinely perform fistulagrams and angioplasties, separately billing federal healthcare programs for what were risky and often unnecessary procedures," the complaint alleged.

This was contrary to what was understood by the compliance department at Fresenius Medical Care (FMC). "FMC's Corporate Compliance Department expected that if an interventionalist did not believe a fistula was necessary, they would communicate this to the patient's referring dialysis clinic or nephrologist," the complaint stated. "In practice, the interventionalists almost always performed a fistulagram at the initially referred appointment. The dialysis clinic and nephrologist were rarely, if ever, consulted, at any point."

Competitions Allegedly Encouraged More Procedures

The complaint describes how compensation and marketing allegedly were designed to increase traffic. Compensation for physicians was based partly on the volume of FVC's billing for procedures. At some FVACs, interventionalists were offered a productivity bonus that was based on the total number of procedures they performed every year above 1,000, the complaint alleged. The chief medical officer at FVC allegedly told interventionalists to review the number of their procedures per day (PPD), and they were given summaries of their PPDs vs. other FVACs.

Marketing teams at FVC were given a geographic region to promote the CTE model and regional directors got a salary and bonus based on performance, the complaint alleged. Every FVAC had baseline goals of monthly procedures. "In staff meetings at the Brooklyn and Staten Island FVACs, managers presented those target volume numbers. Managers wrote these targets on the white boards in the staff lounges," the complaint alleged. "Front desk employees and nurses received financial awards for meeting target goals. FVAC physicians were aware of these minimum procedure thresholds."

FVACs started holding contests to increase the volume of procedures performed. For example, in 2014, a senior director of sales and marketing in Staten Island announced a contest for the north region, with a goal of reaching 400 procedures in the third quarter. "Sales employees participated in other contests held by FVC to incentivize these employees with bonus increases tied to growing new patient referrals," the complaint alleged.

There were other contests. In the "Fall Follow Up Contest" in fourth quarter 2015, employees were ranked on performance. "The main metric used was the number of new patients each employee brought to FVC," the complaint alleged.

Then there was the FVC flyer for a competition called the "Summer Sizzle." It promised rewards for staff at FVACs "with the greatest per day increase in the

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number of procedures from May through July 2015," the complaint alleged.

"FVACs were to 'compete' against each other for the greatest procedure increase. Rewards were to be offered to the top three FVACs in the nation and the top FVAC in every region," the complaint alleged. Winners of the competition were supposed to get a $100 gift card and 10% hike in their quarterly bonuses.

That got some attention from compliance. "In a conference call on May 21, 2015, to address 'concerns' about this competition, FMC's Head of Compliance acknowledged that, 'we shouldn't be performing or billing for non-medically necessary procedures,'" according to the complaint.

CCOs Generally Have to 'Build Alliances'

It's surprising DOJ didn't name any individuals in the FCA complaint, said David Hoffman, president of David Hoffman & Associates P.C., in Philadelphia. "Where is the individual accountability? The defendant is a company. Buildings don't insert fistulas or do angioplasty. Any kind of deterrence would require individuals as part of this False Claims Act matter." More often whistleblowers are adding individuals as co-defendants to FCA complaints against corporations, a trend that's consistent with the DOJ's Individual Accountability Policy but has taken on a life of its own, according to whistleblower attorneys.[3] They say that happens far less when DOJ takes the ball, although that may change now that Deputy Attorney General Lisa Monaco late last year "reinstated" the Yates memo.[4] The Monaco memo stated, "To receive any consideration for cooperation, the company must identify all individuals involved in or responsible for the misconduct at issue, regardless of their position, status, or seniority, and provide to the Department all nonprivileged information relating to that misconduct."[5]

Hoffman also said the allegations make him wonder about Fresenius' compliance culture. How do companies get to a culture of compliance? "You have to build alliances," he said. "A compliance officer is not going to succeed alone in shutting something like this down. You have to be aligned with the general counsel and, I would hope, with the chief medical officer, and you would want to be aligned in some ways with the CEO in terms of the risks associated with the company." When the compliance officer is unable to build alliances and gets "overwhelmed," you have a breeding ground for whistleblowers, said Hoffman, a former federal prosecutor. "There have been discussions of compliance officers as whistleblowers, but it takes a lot for people to go from compliance to being whistleblowers."

Preferably, compliance officers hear from people internally about problems and raise them to the CEO and the board. "You make your voice heard and if there is nothing that's going to be done, then you have no choice but to leave," Hoffman said.

Markey said the whistleblower case was filed against FVACs nationwide, but DOJ's complaint in intervention only names clinics in New York. "They could seek to amend the complaint and add clinics in other states," Markey said.

In a statement, Fresenius said, "Our network of vascular centers is leading efforts to reduce total healthcare costs and improve patient outcomes by expanding access to innovative and less-invasive procedures. Our policies are intended to result in a high standard of care and compliance with government regulations. We dispute the allegations contained in both the relators' complaint and the U.S. government's complaint and intend to vigorously defend the litigation."

Contact Hoffman at dhoffman@dhoffmanassoc.com and Markey at jmarkey@cohenmilstein.com. ✧

Endnotes

1. U.S. Department of Justice, U.S. Attorney's Office for the Eastern District of New York, "United States Files Claims Alleging Fresenius Vascular Care, Inc. Defrauded Medicare and Other Healthcare Programs by Billing for Unnecessary Procedures Performed on Dialysis Patients," news release, July 13, 2022, https://bit.ly/3B0UIxs.
2. United States v. Fresenius Vascular Care, Inc. Civil Action No. 14-CV-3505 (E.D. N.Y., July 12, 2022), https://bit.ly/3ck915M.
3. Nina Youngstrom, "Whistleblowers Are Setting Their Sights on Doctors in Corporate FCA Cases, Lawyers Say," *Report on Medicare Compliance* 31, no. 19 (May 23, 2022), https://bit.ly/3B0god4.
4. Sally Quillian Yates, "Individual Accountability for Corporate Wrongdoing," memorandum, September 9, 2015, http://bit.ly/2W9KsQe.
5. Nina Youngstrom, "Deputy AG 'Reinstates' Yates Memo, Links It to Corporate Culture," *Report on Medicare Compliance* 30, no. 40 (November 8, 2021), https://bit.ly/3n0tUFE.

In Fraud Alert, OIG Cites 'Suspect' Telehealth Characteristics

In a special fraud alert posted July 20, the HHS Office of Inspector General (OIG) warns physicians and nonphysician practitioners (NPPs) to tread carefully "and use heightened scrutiny" when entering into arrangements with telemedicine companies.[1] Practitioners could run afoul of the Anti-Kickback Statute (AKS) and other federal laws if they accept fees for ordering medically unnecessary services, for example, that are reimbursed by federal health care programs. The alert, which is based on several years of enforcement in the telemedicine space, describes "suspect characteristics" that should help practitioners identify questionable arrangements.

Sample Compliance Committee Charter

Here's an example of a charter for a governance, compliance and ethics committee. It appears in the Health Care Compliance Association's *Healthcare Compliance Forms and Tools* and was developed by Parkland Health and Hospital System.[1]

Sample Governance, Compliance, and Ethics Committee Charter

Governance, Compliance, and Ethics Committee Charter	Published: [DATE]
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The organization is committed to developing a governance system that is informed by relevant best practices and to fostering a culture of compliance that emphasizes integrity, ethical conduct, and accountability. To facilitate the fulfillment of those commitments, the Board of Managers (Board) has authorized the formation of a Governance, Compliance, and Ethics Committee (Committee), and it has approved the following charter to set forth the purposes, structure, authority, and duties and responsibilities of the Committee and its members.

Purpose	The Board has oversight authority with respect to the system's governance practices; the operations and efficacy of its Compliance and Ethics Program (Compliance Program); and compliance with applicable federal and state laws, regulations, and administrative rules. The Committee is a standing committee of the Board and is responsible for assessing the effectiveness of the Compliance Program as well as oversight of the performance of the chief compliance and ethics officer (CCO) and the Compliance and Ethics Department (Department). The Committee shall also be responsible for driving Board development, orientation, education, and self-assessment. The Committee shall make periodic reports to the Board on all matters being handled by the Committee. The executive liaisons to the Committee shall be the CEO, the general counsel, the chief governance officer, and the CCO, all of whom shall assist the Committee and the Committee chair in discharging their responsibilities. The CCO shall report to the CEO and to the Committee.
Membership, Meetings, Minutes, and Committee Action	The Committee shall be chaired by a member of the Board and shall consist of at least two other Board members. The Committee will follow the operating guidelines for membership, meetings, minutes, and committee actions as authorized by the Board and as amended from time to time. The Committee will meet with such frequency and at such intervals as it determines necessary to fulfill its duties and responsibilities, and in any case not less than four times per year. A majority of the Committee shall constitute a quorum for the purpose of conducting business.
Governance Responsibilities	In fulfilling its charge related to governance, the Committee is responsible for the following activities and functions, among others: • In consultation with the Company's executive management team, periodically considering the composition of the Board to determine whether additional expertise and skills would facilitate the Board's work, for possible recommendation to the [Administrative Body]; • As needed, assisting the chair of the Board with member recruitment; • Developing a description of the responsibilities and expectations of a Board member, including statutory and fiduciary duties; • Overseeing Board members' development, including orientation and annual educational plan; • Meeting regularly with the executive liaisons to the Committee to discuss and review Board governance activities. Among other things, the executive liaisons to the Committee will be responsible for researching and updating the Committee on pertinent educational opportunities; and • Developing and leading an annual self-evaluation by the Board as well as Board effectiveness assessment.

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OIG emphasized it's not trying to dampen legitimate telehealth arrangements. "OIG is aware that many Practitioners have appropriately used telehealth services during the current public health emergency to provide medically necessary care to their patients," the alert said.

The alert is a different spin on individual accountability, said attorney Kyle Gotchy, with King & Spalding. It addresses the accountability of physicians and NPPs who are in a position to order or prescribe items, such as genetic testing, durable medical equipment and wound care items, that are the focus of telemedicine schemes, he said. "With this special fraud alert, there will be less room for practitioners to say 'I didn't know. I am using it as a side hustle so I didn't do any due diligence,'" Gotchy said. "That will have less weight with enforcers."

According to the alert, OIG and the Department of Justice (DOJ) have investigated a number of criminal, civil and administrative fraud cases where providers got kickbacks from telemedicine companies for improperly ordering or prescribing services. The practitioners and telemedicine companies were held liable for violating the AKS, False Claims Act and other laws. "While the facts and circumstances of each case differed, often they involved at least one Practitioner ordering or prescribing items or services for purported patients they never examined or meaningfully assessed to determine the medical necessity of items or services ordered or prescribed," the alert stated. Also, the amount of money that telemedicine companies paid practitioners often "correlated" with the volume of items or services they ordered or prescribed that are reimbursed by federal health care programs. "These types of volume-based fees not only implicate and potentially violate the Federal anti-kickback statute, but they also may corrupt medical decisionmaking, drive inappropriate utilization, and result in patient harm," OIG said.

OIG: Seven Suspect Characteristics

Based on their enforcement experience, OIG and DOJ developed a list of suspect characteristics of practitioner arrangements with telemedicine companies that could indicate a higher risk of fraud and abuse:

- "The purported patients for whom the Practitioner orders or prescribes items or services were identified or recruited by the Telemedicine Company, telemarketing company, sales agent, recruiter, call center, health fair, and/or through internet, television, or social media advertising for free or low out-of-pocket cost items or services.

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Compliance and Ethics Responsibilities	In fulfilling its charge related to the Compliance Program and the Department, the Committee is responsible for the following activities and functions, among others: • **Oversight of the Compliance Program:** Overseeing the structure, operation, and efficacy of the Compliance Program and, more specifically, the following: ◦ Promoting a systemwide organizational culture focused on compliance and ethical behavior and nonretaliation; ◦ Oversight to ensure appropriate accountability for compliance with the fundamental federal and state legal and regulatory requirements that apply to all facets of the Company's mission and work; ◦ Ensuring that the Code of Conduct and Ethics and compliance-related policies and procedures are complete, periodically revised as necessary, and consistently enforced; ◦ Remaining informed with respect to the work of the Executive Compliance Committee (ECC); ◦ Reviewing, on an annual basis, the Compliance Program risk assessment and associated work plan, which includes auditing and monitoring initiatives; ◦ Periodically reviewing management's responses to compliance-related inquiries and requests from federal and state legislators, regulators, and/or enforcement officials; ◦ Ensuring that the Board is apprised of significant developments relating to the compliance expectations of federal and state regulators and enforcement officials; and ◦ Receiving and reviewing periodic reports from the CCO on the following matters, among others: ▪ The development of the Department, the adequacy of its resources, and progress against the annual work plan; and ▪ Key compliance initiatives undertaken by the organization. • **Annual Compliance Program Review** ◦ At least once every three years, the Committee, in consultation with the CEO, will commission an external review of the Compliance Program to be conducted by an independent third party. ◦ In the interim years, the Committee will receive an assessment report from the CCO as to the operation and effectiveness of the Compliance Program. ◦ At least annually, the Committee will receive and review a report from the ECC demonstrating oversight of the Compliance Program as evidenced by operating in conformance with the ECC Charter. • **Compliance Reporting:** On a regular basis, the CCO will provide the Committee and/or the chair a report summarizing the following: ◦ The receipt, investigation, tracking, and resolution of concerns reported through the Disclosure Program; ◦ Audits, reviews, and/or investigations by government agencies; ◦ Internal reviews and/or audits regarding compliance matters; ◦ Overpayments to federal healthcare programs; and ◦ Any employment or engagement of an individual or entity who is currently, or is likely to be, excluded, debarred, suspended, or otherwise declared ineligible to participate in federal healthcare programs or federal procurement or nonprocurement programs. • **Outside Expertise** ◦ The Committee will engage outside experts, as needed, to fulfill its duties. ◦ When warranted, based on a potentially significant, adequately substantiated allegation against a member of senior management (i.e., senior vice president or above), the Committee has the ability to directly supervise a compliance investigation through the engagement of outside legal counsel, in coordination with the general counsel, as appropriate. • **Oversight of the CCO** ◦ In consultation with the Board and the CEO, annually evaluating the performance of the CCO; ◦ Prior to any action being taken regarding the hiring or termination of the CCO, the Committee must be consulted; and ◦ At least annually, or as needed, meeting with the CCO in a one-on-one, closed Committee session. • **Oversight of the Department** ◦ Reviewing and approving annually the budget for the Department and any revisions to a previously approved budget for the Department. Before submitting a proposed annual budget, or revision thereto, to the Committee, the CCO shall review the proposal with the CEO and the chief financial officer; ◦ Periodically assessing the Department, including span of control and adequacy of staffing levels, expertise, and resources. • **Training:** Completing, on an annual basis, compliance-related training. • **Conflict of Interests:** Reviewing and overseeing compliance with the system's conflict-of-interests policies. • **Board Reporting:** Reporting to the Board at its regularly scheduled meetings.
Other Responsibilities	At least annually, in consultation with the CCO and the general counsel, the Committee will review its Charter and make recommendations to the Board regarding any revisions it determines appropriate and warranted. The Committee will perform such other duties as may be assigned to it by the Board from time to time.

Endnotes

1. "Sample Governance, Compliance, and Ethics Committee Charter," Healthcare Compliance Forms and Tools (Eden Prairie: Health Care Compliance Association, 2022), https://bit.ly/3IYzO3Y.

- "The Practitioner does not have sufficient contact with or information from the purported patient to meaningfully assess the medical necessity of the items or services ordered or prescribed.
- "The Telemedicine Company compensates the Practitioner based on the volume of items or services ordered or prescribed, which may be characterized to the Practitioner as compensation based on the number of purported medical records that the Practitioner reviewed.
- "The Telemedicine Company only furnishes items and services to Federal health care program beneficiaries and does not accept insurance from any other payor.
- "The Telemedicine Company claims to only furnish items and services to individuals who are not Federal health care program beneficiaries but may in fact bill Federal health care programs.
- "The Telemedicine Company only furnishes one product or a single class of products (e.g., durable medical equipment, genetic testing, diabetic supplies, or various prescription creams), potentially restricting a Practitioner's treating options to a predetermined course of treatment.

- "The Telemedicine Company does not expect Practitioners (or another Practitioner) to follow up with purported patients nor does it provide Practitioners with the information required to follow up with purported patients (e.g., the Telemedicine Company does not require Practitioners to discuss genetic testing results with each purported patient)."

'It's Almost a Negative Halo Effect'

Because there has been an "explosion in the number of telemedicine start-ups, it can be challenging for practitioners to distinguish between legitimate and illegitimate partners in this area," Gotchy said. Even though OIG makes that distinction, it's deploying more tools and data analytics to monitor provider activities and reimbursement across the board, he said. This raises the stakes for everybody. "It's a little unfortunate, but it's a case where you have the bad actors compelling this increased oversight," Gotchy said. "It's almost a negative halo effect for the rest of the players out there."

Over time, the telehealth areas that OIG pursues will evolve. OIG and DOJ have targeted telefraud schemes that were "not that creative and easy to replicate," he said. But later this year and in 2023, as OIG starts to release more mainstream telehealth audits from its work plan (e.g., audits of Medicare Part B telehealth services during the COVID-19 public health emergency), "they will identify additional programmatic vulnerabilities that will inform their work going forward," Gotchy said. "We are already seeing them look into the legitimacy of claims for the telemedicine visit itself."

OIG took pains to say that not all telehealth is bad, said attorney Thomas Ferrante, with Foley & Lardner LLP. "For most people, the telehealth expansion has been positive, but increased use translates into increased likelihood of bad actors as well," he said. "These bad actors are rubber-stamping orders and using only a quick phone call without enough medically necessary information. That is telefraud not telehealth. What this fraud alert does is pull enforcement elements of the past two to three years and flags the guardrails."

Contact Gotchy at mkgotchy@kslaw.com and Ferrante at tferrante@foley.com. ✧

Endnotes

1. U.S. Department of Health & Human Services, "Special Fraud Alert: OIG Alerts Practitioners To Exercise Caution When Entering Into Arrangements With Purported Telemedicine Companies," July 20, 2022, https://bit.ly/3z0V3xk.

OIG Audit of Critical Care Finds High Error Rate; No Extrapolation

In a Medicare compliance audit of critical care services provided by Lahey Clinic in Burlington, Massachusetts, the HHS Office of Inspector General (OIG) found a high error rate.[1] But the overpayment amount was small and OIG didn't extrapolate it.

Lahey Clinic is a multidisciplinary physician practice and teaching affiliate of Tufts University School of Medicine. OIG audited a stratified random sample of 100 inpatient admissions that included 1,410 critical services. Medical records for 10 of the admissions, with 92 critical care services, were reviewed by an independent medical reviewer.

The findings: Lahey didn't comply with Medicare requirements for 56 critical care services and was overpaid $6,015 during the audit period of Jan. 1, 2017, to March 31, 2019. Lahey billed when the patients had conditions that didn't indicate critical care services were medically necessary or "when the physician didn't directly provide services at the level of care required for critical care services," OIG contended. Forty-one services should have been billed with the CPT code for subsequent hospital care, and 13 services didn't meet Medicare requirements for critical care or another E/M service. Lahey billed another two critical care services with CPT code 99291 (critical care, first 30 to 74 minutes) when it should have used 99292 (critical care, each additional 30 minutes).

"They did not extrapolate because they limited the audit to 10 admissions instead of the usual 100 due to the resource-intensive effort required to perform a medical review," said Ronald Hirsch, M.D., vice president of R1 RCM. OIG recommended Lahey return the overpayments and identify and refund any potential additional overpayments in accordance with Medicare's 60-day overpayment refund rule.

In a written response, Lori Dutcher, chief compliance officer for Beth Israel Lahey Health, said it agrees with 16 of OIG's findings but not the other 40. For those, "our analysis of the medical records concluded that critical care services were appropriately provided and supported," she wrote. Lahey is determining whether it owes money under the 60-day rule and will refund money if that's the case. ✧

Endnotes

1. U.S. Department of Health & Human Services, Office of Inspector General, "Medicare Critical Care Services Provider Compliance Audit: Lahey Clinic, Inc.," A-03-20-00002, July 19, 2022, https://bit.ly/3Oq9FvZ.

Certification Raises CCO 'Risk Profile'

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The new DOJ policy also would require companies that resolve criminal cases to submit annual self-reports on the state of their compliance programs, and may extend to the CEO and chief compliance officer certifying "that all compliance reports submitted during the term of the resolution are true, accurate and complete," Assistant Attorney General Kenneth Polite said in a March speech.[2]

He said it's not meant to be "punitive." Certifications are designed to "empower" compliance officers and ensure they have "true independence, authority and stature within the company."

In fact, they may "elevate the importance of the compliance function," said Mark Pastin, president of the Health Ethics Trust in Alexandria, Virginia. "It's sending a signal to organizations that compliance is serious." And compliance officers who are expected to sign certifications should be in upper management, a reminder of the influence the compliance role should have. "An attestation to the federal government is a weighty matter," he noted.

The consequences for signing a certification and not delivering on it can be severe: charges under 18 U.S.C. § 1001 (making false statements). "Martha Stewart and thousands of others went to jail for violating it," Trusiak said. And he warns against "omnibus" certifications, such as attesting to compliance with all applicable laws and regulations, in any context. "No provider is in compliance at any one time with all applicable rules, regulations, laws and statutes. That is a recognition of the density and complexity of operating in the health care environment."

'You Have a Voice in Negotiating That Language'

Because the stakes are high, compliance officers shouldn't sign the DOJ certification or any compliance attestation until they're confident about what they're attesting to. Over time, the language may change as U.S. attorneys negotiate pleas and deferred prosecution agreements and go back and forth with defense attorneys, said Trusiak. "If you're uncomfortable with that language, you need to address it then and there. You can't accept some statement [from leadership] of, 'We understand you have resource concerns and they might impede your ability to certify. We will address it in next year's budget,'" he said. "You need to recognize you have a voice in negotiating that language because it is your certification."

It's also a good idea for compliance officers to think broadly about their exposure, beyond the certification in potential criminal cases. In addition to the compliance officer caught up in the potential self-disclosure, Trusiak has taken on another compliance officer client in the past two months in connection with the discharge of their compliance responsibilities. This compliance officer is named in a lawsuit, along with their former employee, over a failed acquisition. Because he had participated in due diligence in preparation for the merger, the compliance officer was drawn into the lawsuit. "When you are involved in a matter that falls within 'duties that are otherwise assigned,' such as mergers, delineate what you are doing and not doing and also look at [your employer's] D&O insurance and see if you're a covered official and whether an event is covered as a claim if it goes south." The compliance officer is paying out of pocket for legal expenses because the former employer's D&O insurance didn't cover him.

The Role of Compliance Committee Minutes

It's important for compliance officers to "recognize material risks as they come along," he said. "These are significant risks that are not set forth in the specific details of your job description." When their job takes them beyond core compliance responsibilities (e.g., auditing the work plan, exclusion screening, ensuring contracts are signed), he suggested compliance officers "memorialize what you are being asked to do" (e.g., help manage a corporate integrity agreement, due diligence for mergers and physician practice acquisitions). "Be transparent. Share with all relevant people what you did and didn't do and maintain a mirror file of important communications." If there's an enforcement action or regulatory concern years later and the compliance officer has left the organization, they won't be able go back and get the files.

Trusiak also suggested having the minutes of the compliance committee reviewed and accepted by the board. "Boards often review and accept minutes of the finance committee because it's critically important to the organization," Trusiak said. The same should apply to the compliance committee. "If everything goes south, you can say, 'The minutes were reviewed by the board, and the board was invested in what I recommended.'" He also thinks a board member should serve on the compliance committee, which ideally hears about both the positive

CMS Transmittals, July 15-21

Transmittals

Pub. 100-04, Medicare Claims Processing

- Modification of Existing Common Working File (CWF) Editing for Preventive Services, Trans. 11504 (July 21, 2022)

Pub. 100-20, One-Time Notification

- Corrections to Processing of Canceled Home Health Notices of Admission and of Period Sequence Edits, Trans. 11503 (July 21, 2022)

aspects of what compliance officers have accomplished in the previous quarter as well as resource constraints that handcuff them. Make sure you're "frank in the compliance committee relative to discharging material risk events," Trusiak said.

Compliance officers also may want to explore whether and how their employer's D&O insurance protects them, Trusiak said, mentioning a blog on the topic.[3] "Detail is important," he noted. "Do not inquire and be satisfied with a statement along the lines of, 'You are covered.'" Compliance officers should ask questions about whether they are an insured person, how a claim is defined, how legal fees are paid, whether protection extends after they leave the organization and whether there's a cap on legal fees.

Language Is Part of 'Settlement Terms Anyway'

The DOJ certification is also another reason to ensure, "well before being in the crosshairs of DOJ," that companies have a process to assess their compliance programs, said Matthew Krueger, former U.S. Attorney for the Eastern District of Wisconsin. "It's best to periodically review and test the compliance program against objective standards so if you are in the compliance officer role you have a basis to give certifications," said Krueger, with Foley & Lardner LLP. DOJ has provided a road map of sorts in its *Evaluation of Corporate Compliance Programs*, which was updated in June 2020.[4]

Certifying they have an effective compliance program can be helped by use of "subcertifications" that companies have in place, Krueger said. Larger entities with multiple compliance professionals may want to use subcertifications according to the area they're responsible for (e.g., auditing and monitoring, training and education) so the chief compliance officer can rely on their subordinates' certifications, he said.

The language in DOJ's new certification "seems like a fairly broad and reasonable request," said Kirk Ogrosky, former deputy chief of DOJ's fraud section. "This type of language is part of the general settlement terms anyway—the government wouldn't be resolving prior criminal conduct if they thought it was still ongoing."

"The trick here is the compliance officer will be signing a document that may give rise to a Sec. 1001 false statement charge if it is, in fact, false," Ogrosky said. "The ask for a formal sign-off by the CEO and chief compliance officer may trigger some anxiety about what the executives may or may not know. And in large, multinational corporations with thousands of employees, it is really hard for the CEO and chief compliance officer to be certain. But these types of certifications are based on what the CEO and chief compliance officer know at the time of execution and whether they have made diligent and reasonable efforts to assure compliance. All in all, it should not be a big deal or extra burden for a well-run company."

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Endnotes

1. U.S. Department of Justice, "Glencore Entered Guilty Pleas to Foreign Bribery and Market Manipulation Schemes," news release, May 24, 2022, https://bit.ly/3B4tRQW.
2. U.S. Department of Justice, "Assistant Attorney General Kenneth A. Polite Jr. Delivers Remarks at NYU Law's Program on Corporate Compliance and Enforcement (PCCE)," news release, March 25, 2022, https://bit.ly/3IRtDPf.
3. Brian S. Scarbrough and Wade A. Thomson, "Key D&O Insurance Considerations For Companies And Compliance Officers In Light Of The U.S. Government's Settlement With MoneyGram's Chief Compliance Officer," *The Compliance & Ethics Blog*, June 21, 2017, https://bit.ly/3zj1xJs.
4. U.S. Department of Justice, Criminal Division, *Evaluation of Corporate Compliance Programs*, June 2020, http://bit.ly/2Z2Dp8R.

NEWS BRIEFS

◆ **Two Florida women, Analay Rico of Fort Lauderdale and Daylen Diaz of Miami, have pleaded guilty in connection with a conspiracy to falsify clinical trial data, the Department of Justice (DOJ) said July 20.** They were study coordinators at the clinical research site Tellus Clinical Research. According to their plea agreements, they worked with others to defraud clients paying for clinical trial work on treatments for opioid dependency, irritable bowel syndrome and other conditions. "Among other things, Rico and Diaz admitted they falsified data to make it appear as though subjects were participating in the trials when, in truth, they were not," DOJ said.

◆ **The DOJ announced July 20 it charged 36 people in 13 federal districts with criminal charges in connection with fraudulent telemedicine**, cardiovascular and cancer genetic testing, and durable medical equipment schemes.

Endnotes

1. U.S. Department of Justice, "Two Florida Medical Study Coordinators Plead Guilty in Connection with Scheme to Falsify Clinical Trial Data," news release, July 20, 2022, https://bit.ly/3v97Exw.
2. U.S. Department of Justice, "Justice Department Charges Dozens for $1.2 Billion in Health Care Fraud," news release, July 20, 2022, https://bit.ly/3OH1yeR.