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Leveraging CIAs and IAs as a compliance tool: Analyzing trends to identify and mitigate compliance risks for practitioners

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Identifying, monitoring, and addressing potential risk areas is a critical component of an effective compliance program. Indeed, the U.S. Department of Health & Human Services Office of Inspector General (OIG) recommends that healthcare organizations participating in federal healthcare programs conduct periodic risk assessments and engage in internal review processes pursuant to which the organization will identify and prioritize risks, develop and implement internal audit work plans related to identified risk areas, and develop and implement corrective action plans in response to the results of any internal audits performed.[1]

Identifying potential risks requires compliance personnel to understand the organization's operations and to review and consider numerous sources of information to determine possible compliance challenges that could result in legal, financial, or reputational harm. Understanding government enforcement trends allows healthcare organizations to make informed decisions regarding where to invest their time, energy, and resources.

This article is the second in a series designed to equip compliance personnel with data—derived from recent government enforcement activity—that can help them better understand the government's current enforcement priorities and, thus, more easily identify and rank potential risks to their organization.

Recent corporate integrity agreements (CIAs) and integrity agreements (IAs) imposed by the OIG,[2] and the associated settlement agreements, provide a wealth of information regarding the agency's priorities, areas of focus, and compliance expectations.[3] (IAs are similar to CIAs but typically have a shorter term and contain fewer compliance obligations.) By understanding the circumstances under which the OIG has imposed a CIA or IA, federal healthcare program participants can better understand the agency's enforcement emphasis and identify internal practices that may require closer scrutiny.

Unfortunately, while the OIG maintains a publicly available database of its active CIAs and IAs (and associated materials),[4] the data is not organized in a way that easily allows for quantitative and qualitative analysis. Each article in this series is designed to provide targeted data analysis of recent CIA and IA enforcement activity

related to a specific type of provider or supplier. This article focuses on CIAs and IAs recently imposed on individual healthcare practitioners and/or medical practices. For ease, we refer to these CIAs and IAs, collectively, as "Practitioner Integrity Agreements."

Trends among Practitioner Integrity Agreements

During the period from January 1, 2020, through September 15, 2021, the OIG imposed 27 Practitioner Integrity Agreements (23 IAs and four CIAs). Consistent with the OIG guidance,[5] the determining factor for whether a CIA or IA was imposed appears to have been the size of the organization at issue. All four CIAs were imposed on larger medical practices.[6]

Based on news releases published by the U.S. Department of Justice (DOJ), it appears that most of the Practitioner Integrity Agreements were imposed in connection with a settlement with DOJ of one or more actions brought under the federal civil False Claims Act (FCA).[7] Notably, several of these settlements also included the state attorney general and/or other state authorities as parties settling actions brought under the state equivalent of the FCA for claims submitted to the state's Medicaid program. Overall, five of the 27 Practitioner Integrity Agreements arose from enforcement actions filed in Florida, and four arose from enforcement actions filed in Tennessee.[8]

A study of the Practitioner Integrity Agreements noted above, as well as the corresponding DOJ news releases, settlement agreements, and underlying complaints detailing the actions at issue (to the extent publicly available),[9] reveal certain trends that may be of interest to compliance personnel. Our analysis provides insights into potential risks arising from, among other things, (i) claims for diagnostic tests, (ii) claims for vision care items and services, (iii) coding inaccuracy, and (iv) remuneration provided to referral sources and patients. The specific allegations underlying these Practitioner Integrity Agreements, and the associated compliance obligations imposed through them, can be leveraged as valuable informational tools for medical practices, healthcare practitioners, and other healthcare providers when developing risk management and compliance strategies.

1. Billing of diagnostic tests alleged to be medically unnecessary

For at least six of the Practitioner Integrity Agreements,[10] the alleged conduct included billing for diagnostic tests that were claimed to be medically unnecessary.[11] Notably, the parties to four of these six Practitioner Integrity Agreements include medical practices and/or individual practitioners that specialize in pain management.[12]

- Two of the six Practitioner Integrity Agreements pertaining to diagnostic testing arose from settlements of alleged violations of the FCA in connection with pain providers' ordering of urine drug testing.[13] In both instances, practitioners in medical practices specializing in pain management allegedly ordered urine drug tests for *all* patients at *all* visits without an individualized patient assessment as to whether the urine drug test was medically necessary, and without using those tests for the treatment of their patients.[14] In one case, the medical practice purportedly sent all such urine drug tests to a reference laboratory (in exchange for kickbacks), even though some of the tests (specifically, qualitative urine drug tests)[15] could have been, and previously were, performed by the pain provider in office.[16] In the other case, the medical practice allegedly sent all quantitative urine drug tests to a laboratory that was indirectly owned by the same corporate parent as the pain provider.[17]

- Three of the six Practitioner Integrity Agreements arose from alleged false claims for diagnostic nervous system and/or cardiac system testing that was alleged to be medically unnecessary. Specifically, the allegations underlying these Practitioner Integrity Agreements involved the following diagnostic tests: (i) nerve conduction studies,[18] (ii) autonomous nervous system testing,[19] and (iii) vital system assessment tests.[20] Similar to the allegations in the urine drug testing cases, this diagnostic testing allegedly was medically unnecessary because it was not supported by an individualized patient assessment in the medical record and/or was not used for the subsequent treatment of the patient.[21]

- The sixth and final Practitioner Integrity Agreement involved a slew of diagnostic tests that were alleged to be medically unnecessary, including nuclear stress tests, ankle-brachial index/toe-brachial index testing, Doppler tests, electrocardiograms, pulmonary function tests, chest x-rays, Holter monitors, bone density tests, routine lab tests, echocardiograms, cardiac stress tests, peripheral arterial studies, sleep studies, and renal scans.[22]

2. Alleged upcoding or coding for noncovered services

At least four of the Practitioner Integrity Agreements arose from allegations of upcoding (i.e., coding for services that are more expensive than those actually performed) or coding for a covered service when a noncovered service was performed.[23]

- Two of the Practitioner Integrity Agreements arose from alleged false claims pertaining to electro-acupuncture. In both instances, a physician and/or medical practice allegedly submitted false claims to Medicare (and in one instance, to the Tennessee Medicaid program as well) because the claims included Healthcare Common Procedure Coding System (HCPCS) codes for implantable neurostimulator devices when, in reality, the underlying services involved the application of an electroacupuncture device.[24] Medicare and Tennessee Medicaid do not reimburse for electroacupuncture devices as neurostimulators, nor did they otherwise cover acupuncture (at least during the time period at issue). Notably, a DOJ news release regarding one of these cases indicated that the case was "one of many of its kind involving electro-acupuncture billing that U.S. Attorneys' Offices across the United States have worked diligently to resolve," suggesting that more settlements and Practitioner Integrity Agreements regarding this issue may be forthcoming.

- The other two Practitioner Integrity Agreements involved allegations of upcoding. In one instance, a Florida-based dermatologist and her dermatology practice allegedly billed Medicare for higher-reimbursing adjacent tissue transfers using 14000-level Current Procedural Terminology (CPT) codes when, in fact, they performed complex wound repairs that should have been billed using lower-reimbursing 12000- or 13000-level CPT codes.[25] In the other instance, a Kentucky-based podiatrist and his podiatry practice routinely billed for six-or-more toenail debridement using CPT code 11721, when a lesser procedure (e.g., a nail trim) typically had been performed.[26] Notably, the latter Practitioner Integrity Agreement included a statement of facts in which the practice and its podiatrist owner agreed and stipulated to certain facts. Several facts appear to have been significant.

    - First, the government examined all claims for nail trims or nail debridements submitted by the podiatry practice during a six-year period and found that the practice "principally submitted claims using CPT Code 11721" (i.e., the highest reimbursing code). For example, in 2018, the practice submitted 3,806 claims using CPT code 11721 (debridement, six or more nails), but only 277 claims for all other lower-reimbursing codes for nail debridement or nail trimming.

- Second, the practice's billing pattern also indicated a "sharp decline" in the use of lower-reimbursing CPT code 11719 (trimming nails, any number) beginning in 2013, which coincided with the practice becoming informed that the Centers for Medicare & Medicaid Services had cut payment for that CPT code in half.
- Third, the practice's debridement medical records contained "cloned language" (i.e., "identical, word-for-word" phrasing) that appears to have been the result of "carrying forward" provider notes and "template use" rather than "individualized documentation of patient symptoms and the care rendered."

3. Alleged false claims pertaining to vision care

At least four of the Practitioner Integrity Agreements arose from alleged false claims for vision care items and/or services.[27]

- Two of these Practitioner Integrity Agreements relate to claims for intravitreal injections of Eylea and/or Lucentis, which the OIG identified as a risk area in its 2019 Work Plan.[28]
  - In one such case, a Florida-based ophthalmology practice allegedly submitted false claims for treatments using Eylea and Lucentis by engaging in the practice of "multi-dosing" (i.e., using a single drug vial to provide doses to multiple patients). As described in the settlement agreement, Eylea and Lucentis are intended to be used on a single-use basis, and thus this alleged multi-dosing practice was claimed to result in excess reimbursement from federal healthcare programs for the drugs at issue.[29]
  - In the second case, a Tennessee-based ophthalmology practice purportedly submitted false claims for separately reimbursable evaluation and management services (billed with modifier 25) provided on the same day as intravitreal injections of Lucentis. As explained in the operative complaint, Medicare pays for an intravitreal injection as part of a global surgical package but will make a separate payment for other services provided by the same physician on the same day as the global surgery if the services are "significant and separately identifiable." Allegedly, the ophthalmology practice routinely billed modifier 25 in connection with Lucentis injections, despite a lack of documentation in the medical record to justify use of the modifier.[30]
- A third Practitioner Integrity Agreement pertaining to vision care arose from a review of claims data conducted by the U.S. Attorney's Office, in which a Texas-based optometrist was determined to be "one of the most significant statistical outliers in the nation" for certain categories of claims.[31] The government alleged that the optometrist billed Medicare for medically unnecessary services and tests (including punctal plug insertion, sensorimotor testing, vision therapy/orthoptics, and amniotic membrane placement) that were not warranted by the patient's condition or were repeated on the same patient more often than what would be medically reasonable or necessary.
- The fourth Practitioner Integrity Agreement arose in connection with an FCA action brought by the US and Connecticut against an optician and an optical retail store owned by that optician.[32] Allegedly, the optician and store (i) submitted claims to Medicaid for multiple pairs of eyeglasses for beneficiaries under the age of 21, despite spare eyeglasses not being covered under the Connecticut Medicaid program, and (ii) for every pair of eyeglasses billed to Medicaid, also used procedure code V2799 (for miscellaneous vision services or items) when such services and items were never provided or, if provided, were not medically

necessary.[33]

4. Alleged violations of Anti-Kickback Statute

Finally, at least six Practitioner Integrity Agreements arose from alleged violations of the federal healthcare program Anti-Kickback Statute.[34] Four of these involved allegations that a healthcare practitioner or medical practice accepted kickbacks in exchange for making referrals.

- One of the Practitioner Integrity Agreements pertained to urine drug testing (and also is described above). For that Practitioner Integrity Agreement, the alleged kickbacks took the form of fee splitting; specifically, the medical practice specializing in pain management allegedly was paid a portion of the payer reimbursement received by the reference laboratory for all urine drug tests ordered by the medical practice from the reference laboratory.[35]
- A second Practitioner Integrity Agreement arose from alleged "sham speaker program fees" paid by a pharmaceutical manufacturer to a Florida-based pain management physician as an inducement for the physician to prescribe the manufacturer's drug.[36] Notably, a few months after this Practitioner Integrity Agreement was implemented, the OIG published a Special Fraud Alert regarding speaker programs by pharmaceutical and medical device companies, suggesting heightened scrutiny in this area.[37]
- The other two Practitioner Integrity Agreements arose from FCA settlements involving alleged kickbacks provided by hospitals to physicians.
    - In one such case, a physician who served as a major referral source for four jointly owned hospitals allegedly was paid up to $15,000 per month by the hospitals' corporate owners for "overlapping medical directorships."[38] These medical directorships were alleged to be sham arrangements because (i) the payment amounts at issue were unusually high, (ii) the underlying medical director agreements provided only vague services descriptions, and (iii) it seemed unlikely that the physician actually provided medical director services in an amount that could justify the payments, as he had a full clinical practice and his timesheets were not timely and contained vague entries for large amounts of time that were nearly identical from month to month.[39]
    - With respect to the other Practitioner Integrity Agreement, the US and Oklahoma alleged that several arrangements between an orthopedic surgery practice and surgical hospital were problematic.
        - First, two of the practice's orthopedic surgeons allegedly leveraged their position as significant referral sources to obtain free or below-fair-market-value office space, employees, and supplies from the hospital.[40] For example, according to the relator's complaint, the hospital paid the majority of the cost of personal medical assistants for the two orthopedic surgeons, which would otherwise have been borne directly by the orthopedic surgeons.[41] The relator also alleged that the hospital provided office space, at no charge, to one of the orthopedic surgeon's employees, who used the space to manage the orthopedic surgeon's personal affairs.
        - Second, the same two orthopedic surgeons, who had an ownership interest in the hospital, allegedly were provided with preferential buyback provisions and payments for their equity in the hospital that were above fair market value.[42]

- Third, the relator alleged that the hospital paid compensation in excess of fair market value for the services furnished by the physician practice and certain of its orthopedic surgeons.[43]

While most of the Practitioner Integrity Agreements related to the Anti-Kickback Statute involved the alleged *receipt* of kickbacks by a healthcare practitioner, one involved the alleged payment of kickbacks by a physician and his medical practice. Specifically, a New York–based otolaryngologist and his medical practice were alleged to have paid cash tips, rent in excess of fair market value, and other improper remuneration to medical management companies in adult homes to induce those companies to make them the exclusive provider of allergy testing, otolaryngology examinations, and related physician services for the adult home residents.[44]

Finally, there also was one Practitioner Integrity Agreement that involved the alleged provision of kickbacks to federal healthcare program beneficiaries. Specifically, a Practitioner Integrity Agreement was imposed on a Florida-based cardiologist and his medical practice due, in part, to their alleged waiver of Medicare copayments for patients regardless of financial hardship.[45]