CIAs and IAs in 2022 – A Year in Review

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Over the course of 2022, 25 providers and organizations entered into Corporate Integrity Agreements (CIAs) or Integrity Agreements (IAs) with the Department of Health and Human Services (HHS) Office of Inspector General (OIG), compared to a combined 31 CIAs and IAs executed in 2021.[1] CIAs and IAs are negotiated by the OIG with health care providers and organizations as a means to settle allegations relating to violations of civil false claims statutes. In exchange for providers or organizations agreeing to the terms and conditions of the CIA or IA, the OIG agrees not to pursue exclusion of the provider or organization from participation in Medicare, Medicaid, or other Federal health care programs.

IAs and CIAs contain common provisions, including requirements that align with the elements for an effective compliance program set forth by the OIG in its guidance publications. CIAs with entities typically span for a period of five years and contain common provisions such as requiring designation of a Compliance Officer and establishment of a Compliance Committee; development of written standards and policies; and implementation of an employee training program. Most CIAs also require the subject party to retain independent review organizations (IROs) to conduct annual reviews, including claims reviews and systems reviews to analyze organizational systems and processes related to claims payments.

While CIA describe obligations that have been standard provisions for many years, towards the end of 2022 the OIG made a few minor revisions to some compliance-related obligations in its agreement. The OIG also implemented a new requirement that parties develop a transition plan a year prior to the end of the CIA to describe how their compliance programs will continue to carry forth obligations that were required under the CIA following termination of the CIA. Transition Plans must be approved by parties' governing boards.

With regard to revisions to compliance-related obligations, the OIG increased its authority and oversight in ensuring that Compliance Officers do not perform

noncompliance job responsibilities that may detract from their roles. While CIAs have historically required that noncompliance job responsibilities be limited and not interfere with the Compliance Officer's ability to perform CIA-required duties, the revision grants the OIG express discretion in determining that a noncompliance responsibility may interfere with the Compliance Officer's ability to perform CIA-required duties and must be eliminated. The CIA revisions also grant increased responsibilities to Compliance Committees. While previously CIAs included language requiring the Compliance Committee to offer general support to the Compliance Officer in fulfilling his/her responsibilities without specifying particular duties, provisions in the new agreements require the Compliance Committee to specifically oversee policies and procedures, training, and the risk assessment.

While the OIG has always required parties to its CIAs to screen its employees and contractors against the OIG's List of Excluded Individuals/Entities (LEIE) and the System for Award Management (SAM), the OIG expanded these requirements to require screening against publicly available state Medicaid program exclusion lists.

Integrity Agreements

Out of the 25 agreements executed in 2022, seven constituted IAs. While parties to CIAs are health care entities, parties to IAs include individual practitioners and small practices. IAs have a shorter term of three years, rather than the five-year term set forth in CIAs. The 7 IAs executed in 2022 all require the parties to retain an IRO to conduct a claims review as part of its obligations under the agreement. Five of the seven IAs require a claims review to be performed on a quarterly, rather than annual basis.

IAs also contain a provision requiring its parties to report to the OIG if they contract with a third-party billing company. Further, organizations utilizing third-party billing companies are required to certify to the OIG that they do not have an ownership or control interest in the third-party billing company. The third-party billing company must also produce a certification that it screens its employees against federal exclusions lists and provides its employees with training related to Federal health care program billing requirements.

Notable CIAs

In the largest settlement resulting in a CIA in 2022, international pharmaceutical company Mallinckrodt plc was ordered to pay $260 million for allegedly violating the False Claims Act by underpaying Medicaid rebates that it owed to the government based on price increases to its drug H.P. Acthar Gel (Acthar).[2] The government's complaint detailed that Mallinckrodt misrepresented that Achtar was a new drug, which resulted in Mallinckrodt paying a lower Medicaid rebate amount, although Achtar has been on the market since 1952. The increase caused Medicaid to cover the costs of a purported increase in the price of the drug from $50 per vial to $28,000 per vial. Despite several warnings from CMS, Mallinckrodt improperly calculated Medicaid rebates it owed by disregarding all price increases prior to 2013 for Achtar, significantly lowering the Medicaid rebate that it paid. Mallinckrodt also allegedly used a foundation as a conduit to pay illegal co-payment subsidies for Achtar in violation of the Anti-Kickback Statute.

The requirements of the CIA are numerous and require Mallinckrodt to comply with some unique price transparency provisions and monitoring provisions in relation to Medicaid rebate calculations and patient assistance program charities. Specifically, Mallinckrodt is required to establish a risk assessment program and to implement safeguards in relation to executive incentive compensation. The

CIA requires Mallinckrodt to establish an Incentive Compensation Program, which requires it to make certain disclosures related to executive incentive compensation, to implement criteria for employees and executives to satisfy as a prerequisite to earning incentive compensation, and to prohibit and potentially rescind incentive payments for those involved in misconduct or noncompliance with company policies and procedures, its Code of Conduct, or the law.

The CIA also requires Mallinckrodt to establish an Executive Financial Recoupment Program, which mandates forfeiture of incentive awards and bonuses if significant misconduct is discovered by Mallinckrodt in relation to the party receiving the incentive. In relation to individuals involved in significant misconduct, Mallinckrodt also has the discretion to void any unvested stock options, unvested stock appreciation rights, unvested deferred share units, and other unvested rights to receive company common stock.

Mallinckrodt is also obligated to comply with certain requirements related to its independent charity patient assistance program (PAP) activities, including designation of an independent charity group and the establishment of written criteria to ensure that the PAP does not function as a conduit for payments or other benefits to patients and does not impermissibly influence patients' drug choices. Mallinckrodt is also required to take several steps related to pricing transparency for its products. Specifically, the company must post on its website a notice of any planned pricing increases to Achtar or other drug reimbursable by the government at least seven days prior to the increase, including details related to the price change and reason for it. Additionally, the CIA requires a review of Mallinckrodt's systems and processes relating to government pricing functions for government reimbursed products, including, but not limited to processes used to determine average manufacturer price and best price for government reimbursed products.

CIAs with Medical Device Manufacturers

Four of the CIAs executed in 2022 involved settlements with medical device manufacturers. In one settlement, Biotronik, Inc. (Biotronik) agreed to pay $12.95 million to settle allegations that it made payments to physicians for an excessive number of trainings that either never actually occurred or were of little value to trainees.[3] Biotronik allegedly paid honoraria to physicians who briefly appeared at international conferences. The allegations also involved payment for physicians' winery tours, lavish meals, holiday parties, and international business class airfare. Biotronik was allegedly warned by its compliance department that salespeople had too much influence over selecting physicians for the new employee training and that training payments were being over-utilized.

In the largest settlement resulting in a CIA against a medical device manufacturer in 2022, Philips RS North America LLC, f/k/a Respironics, Inc. (Respironics) agreed to pay $24 million to resolve allegations that it violated the False Claims Act by paying kickbacks to durable medical equipment suppliers.[4] Another medical device manufacturer, Essilor of America and Essilor Laboratories (Essilor) agreed to pay $16.4 million to resolve allegations that it violated the Anti-Kickback Statute by inducing providers to order and purchase its optical lenses and equipment for their patients, including Medicare and Medicaid beneficiaries.[5] Finally, medical device manufacturer Vision Quest Industries (Vision Quest) agreed to pay $2.25 million to resolve False Claims Act allegations that it paid kickbacks through excessive compensation offered to sales representatives selling its knee braces, resulting in millions of dollars in annual brace sales for Vision Quest.[6]

The CIA with Biotronik contains provisions outlining obligations related to its speaker programs. Biotronik is required to conduct a business needs assessment for its speaker programs each year, which must be overseen by Biotronik's compliance personnel.[7] Additionally, Biotronik is required to implement a system to track its speaker program arrangements, written agreements, and training programs for all its speakers, and to ensure that speakers are paid based on a documented pre-set structure calculated as within fair market value. The CIA also requires a Speaker Monitoring Program, where Biotronik is required to arrange for its compliance staff or other appropriately trained personnel to attend 15 Speaker Programs a year and conduct live audits of the program.

The CIA with Essilor requires the company to conduct a needs assessment of any co-marketing activity, identifying the business need and describing the purpose of the activity.[8] Essilor is also required to implement a review and approval process for all its discount arrangements. The CIA specifies that co-marketing activity and discount arrangements must be set forth in written agreements, for which remuneration has been set forth in advance and is within fair market value, and which must be maintained in a centralized system. Discount arrangements must also undergo a documented review and approval process, including legal review.

The CIAs with Biotronik, Respironics, and Essilor require the companies to implement a Field Force Monitoring Program to evaluate and monitor interactions between its sales personnel and health care professionals (HCPs) and health care institutions (HCIs), including direct field observations where a monitor is required to attend a certain number of the companies' sales meetings with HCIs and HCPs. The CIAs also require records review of documents such as expense reports, travel and entertainment receipts, and other payments to HCIs and HCPs, as well as the sales notes, e-mails and other correspondence between sales personnel and HCIs and HCPs.

Another notable provision in the Biotronik and Essilor CIAs requires the companies to maintain a system for tracking, monitoring, and auditing its third-party educational activities and other grant and charitable activities. Additionally, the Biotronik and Respironics CIAs each contain a provision requiring the companies to post on their websites a description of the types of payments it makes to physicians and other covered providers through the Centers for Medicare & Medicaid Services (CMS)' Open Payments Data website, and to include a link to the site. The same provision also appeared in a 2022 CIA with a pharmaceutical manufacturer, Cardinal Health 108, LLC (Cardinal Health).[9] That CIA is tied to a settlement in which Cardinal Health agreed to pay $13,125,000 to resolve allegations that it violated the False Claims Act by making upfront payments to its physician practice customers preceding their purchase of any drugs from Cardinal Health.[10]

CIAs Following Billing for Unnecessary Services

Several CIAs in 2022 resulted from providers and their practices billing for services that were not reasonable or medically necessary. The allegations underlying the execution of four CIAs involve violations of the False Claims Act based on the submission of claims for medically unnecessary urine drug testing (UDT).[11] In the largest related settlement, for $24.5 million, Physician Partners of America LLC (PPOA) was alleged to have caused the submission of claims for medically unnecessary UDT by requiring its physician employees to order multiple UDTs at the same time without reviewing the results of initial testing (presumptive UDT) to determine whether additional testing (definitive UDT) was necessary.[12] The toxicology

lab affiliated with PPOA also billed federal healthcare programs for the highest-level UDT. PPOA also allegedly violated the Stark Law by inducing its physician employees to order presumptive UDT through payment of 40 percent of the testing profits to the physicians. No doubt contributing to the high settlement amount, PPOA is also alleged to have subjected patients to genetic and psychological testing before the patients were seen by physicians, without reasonable and necessary determinations. Additionally, PPOA is alleged to have sought compensation for lost revenue during the early days of the COVID-19 public health emergency by requiring its physicians to schedule unnecessary evaluation and management (E/M) appointments with patients every 14 days, rather than every month as had been PPOA's prior practice, and instructing its physicians to bill the E/M visits using inappropriate high-level procedure codes.

To address the many allegations of improper billing for medically unnecessary services, the CIA contains many provisions requiring PPOA to implement clinical quality improvement measures, including through the appointment of a Medical Director and a Compliance and Clinical Oversight Board.[13] The CIA requires the Medical Director to be a member of senior management, to report directly to the Chief Executive Officer, and to be either an M.D. or a D.O. with experience in the field of pain management and urine drug testing. The CIA also requires appointment of a Compliance and Clinical Oversight Board, composed of both employees and non-employees, responsible for an annual resolution summarizing the Board's review and oversight of PPOA's compliance with the CIA requirements. PPOA is also required to create and maintain a report of all test orders, including a description of the type of testing ordered and reason for the test. The Compliance Officer and Medical Director are required to review the testing report to ensure that the tests ordered do not exhibit patterns and practices that are inconsistent with medical reasonableness and necessity standards. The Compliance Officer is also required to review the Testing Report with the Compliance Committee on a quarterly basis. In relation to compliance obligations, the CIA notably requires the appointment of Deputy Compliance Officers in addition to a Compliance Officer.

PPOA was not the only entity to require the designation of compliance personnel in addition to a Compliance Officer. Under its CIA, Providence Health & Services (Providence) is required to designate Regional Compliance Directors and Hospital Compliance Leads to assist with implementing policies, procedures, and practices designed to ensure compliance with CIA requirements.[14] In the underlying settlement, Providence paid nearly $22.7 million to resolve allegations that it fraudulently billed Medicare and Medicaid for medically unnecessary neurosurgery procedures.[15] The health system was alleged to have paid its neurosurgeons based on a productivity metric that provided a financial incentive to perform surgical procedures of greater complexity.

The Providence CIA also requires appointment of a Chief Quality Officer and a Clinical Quality Department, and establishment of a Quality of Care and Patient Safety Program. Additionally, Providence is required to not only engage an IRO, but to retain a Quality Review Organization (QRO), selected by the OIG in consultation with Providence. The QRO is charged with conducting a Clinical Quality Systems Review to assess Providence's quality of care and patient safety, credentialing, privileging, and peer review processes.

Overall, CIAs in 2022 emphasize a focus on transparency and quality of care. The new compliance-related provisions added by the OIG designate specific oversight responsibilities to the Compliance Committee and grant the OIG greater

authority in ensuring that Compliance Officers do not have obligations that detract from their compliance-related responsibilities. Finally, the new transition plan requirement will ensure that organizations continue to carry out obligations required over the course of a CIA beyond the termination of the agreement.

Endnotes

1. *https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp*.
2. *https://www.justice.gov/usao-edpa/pr/mallinckrodt-agrees-pay-260m-settle-false-claims-act-lawsuit-alleging-payment-illegal*.
3. *https://www.justice.gov/opa/pr/medical-device-manufacturer-biotronik-inc-agrees-pay-1295-million-settle-allegations-improper*.
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5. *https://www.justice.gov/opa/pr/essilor-agrees-pay-164-million-resolve-alleged-false-claims-act-liability-paying-kickbacks*.
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7. *https://oig.hhs.gov/fraud/cia/agreements/Biotronik_Inc_08262022.pdf*.
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11. *https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp*.
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13. *https://oig.hhs.gov/fraud/cia/agreements/Physician_Partners_of_America_LLC.pdf*.
14. *https://oig.hhs.gov/fraud/cia/agreements/Providence_Health_and_Services_Washington_03172022.pdf*.
15. *https://www.justice.gov/usao-edwa/pr/providence-health-services-agrees-pay-227-million-resolve-liability-medically*.

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