DOJ Recoups a total of $1.8 Billion from Health Care Fraud in 2020, Laboratory Recoupments Alone Account for Hundreds of Millions


The Department of Justice ("DOJ") **has reported** that in 2020, the government prosecuted dozens of laboratory owners and operators for anti-kickback related offenses responsible for hundreds of millions in alleged federal health care program loses. DOJ recouped a total of $1.8 billion dollars in connection with healthcare fraud allegations.

Since the public health emergency was announced in March 2020, the Centers for Medicare & Medicaid Services, the U.S. Department of Health and Human Services ("HHS"), Office of the Inspector General ("OIG"), and other law enforcement agencies partnered to investigate and prosecute health care fraud from identified risk areas, including unnecessary laboratory testing related to the COVID-19, genetic sequencing, and cardiac panels.

Laboratories prosecuted in the last two years for health care fraud include: UTC Laboratories Inc. (RenC) ($41.6 million), Boston Heath Diagnostics Corporation ($26.7 million), Logan Laboratories Inc. ($41.0 million), Genova Diagnostics ($43.0 million).

According the to the report, "[t]hroughout FY 2020, HHS-OIG issued 178 audit reports and 44 evaluations, resulting in 689 new recommendations issued to HHS operating divisions. HHS operating divisions also implemented 286 recommendations during FY 2020." Laboratory-related audit and evaluation findings are as follows:

- "Medicare Advantage (MA) encounter data continue to lack National Provider Identifiers (NPIs) for providers who order and/or refer durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS); clinical laboratory services; imaging services; and home health services. However, almost all MA organizations have data systems that are able to receive and store these NPIs when providers submit them. In addition, a substantial portion of MA organizations reported that providers already are submitting the ordering provider NPIs on claims or encounter records for DMEPOS, laboratory services, and imaging services. Further, a majority of MA organizations require NPIs to be submitted for their other lines of business. Finally, almost half of MA organizations believe that using NPIs for ordering providers is critical for combating fraud."
- "Total Medicare Part B spending for lab tests increased to $7.6 billion in 2018, despite lower payment rates for most laboratory (lab) tests. The $459.0 million spending increase was driven by: (1) increased spending on genetic tests; (2) ending the discount for certain chemistry tests; and (3) the move to a single national fee schedule. Congress mandated that the Office of Inspector General monitor Medicare payments for lab tests and the implementation and effect of the new payment system for those tests. This report also provides the fifth annual analysis

of the top 25 lab tests by Medicare spending."

Importantly, the report indicates that in 2021 and 2022, DOJ-OIG will have more resources, more complete data, and will therefore be able to provide even more oversight of health care fraud, resulting in "a steady increase in healthcare related audits, inspections, and investigations."

Alere Pays $198.75 Million to Settle False Claims for Allegedly Billing Medicare for Defective POC Devices, Not Charging Copays, and Sending Supplies to Deceased Patients

Alere Inc. and Alere San Diego Inc. (collectively "Alere") have come under fire recently by the U.S. Department of Justice ("DOJ") and other government agencies, agreeing to settle several rounds of accusations of False Claims Act violations for a total of $198.75 million.

The first series of settlements was **announced** by DOJ on July 8, 2021 and cost the company approximately $38.75 million in fines and penalties. Here, the medical device manufacturer was alleged to have billed Medicare for rapid point-of-care testing devices that Alere knew were defective. More specifically, the government alleged that the INRatio blood coagulation monitors (manufactured by Alere) were defective. The monitors were used by Medicare beneficiaries taking anticoagulant drugs to monitor their blood coagulation. Anticoagulants drugs can cause major bleeding when used in access or blood clots and strokes can develop when not enough medication is taken. DOJ alleged that Alere concealed the fact that the device was producing inaccurate results for some patients, resulting in several deaths and hundreds of injured beneficiaries. This practice was ongoing for a total of eight years, according to DOJ.

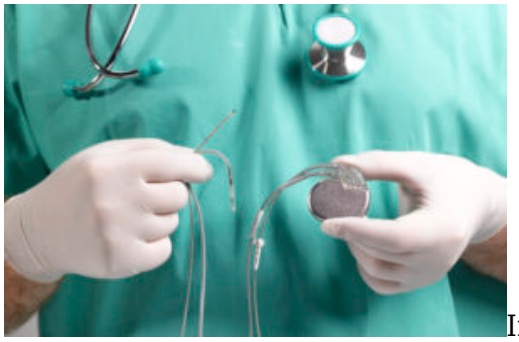
One month after this first massive settlement was announced, the DOJ **announced** an even more sizable settlement with Alere Inc.'s subsidiary, Arriva Medical ("Arriva"), a diabetes testing equipment supplier, totaling an additional $160 million to settle false claims related to an alleged kickback scheme. The DOJ purported that, from April 2010 through December 2016 – immediately prior to Abbott's $5.3 billion acquisition of Alere in 2017 – Arriva (1) regularly waived and failed to collect Medicare beneficiaries' cost-sharing amounts (i.e. copays); (2) sent glucose meters at no cost to patients; and (3) sent diabetic testing equipment to deceased patients.

Medical device makers, durable medical equipment suppliers, and Medicare providers of all sorts should take heed of these recent settlements and implement regular third party compliance and billing audits as part of their Compliance Program to help ensure that practices are aligned with

government expectations and rules. In addition, companies acquiring, merging with, or investing in healthcare entities should incorporate complete third party billing and compliance testing as part of their due diligence in connection with these types of transactions to identify billing-related risks.

If you have any questions, please contact Anne Brendel (**abrendel@goodwinlaw.com**; 415-733-6047) or Matt Wetzel (**mwetzel@goodwinlaw.com**; 202-346-4208).

Patient Stakeholder Group Zeroes in on Medical Device Industry



In recent months, the Kaiser Health Network (part of the Kaiser Family Foundation) has issued three reports scrutinizing the orthopedic industry and its practices. Each report articulates the stakeholder group's concerns over relationships among orthopedic and spinal surgeons, orthopedic implant manufacturers, and their sales representatives. Medical device manufacturers, especially those in the orthopedic space, should pay careful attention.

- **The first report** (June 2021) dives deeply into payments made by medical device makers to orthopedic surgeons who use their products. Kaiser highlights government allegations against orthopedic medical device makers (focusing specifically on the recent **SpineFrontier matter**) that they pay "sham consulting fees" to spinal surgeons for "doing little or not work." Kaiser identifies what it considers to be troublesome payments from medical device makers to surgeons that implant their products, including royalty payments (for "helping to design implants"), speakers' fees ("for promoting devices at medical meetings"), to stock ownership provided in exchange for consulting. Kaiser notes that, from 2013 through 2019, the orthopedic industry has paid $3.1 billion to its surgeon consultants, highlighting the potential to "corrupt medical judgment and tempt surgeons to perform unnecessary and wasteful operations." The patient stakeholder group also spotlights what it considers to be a "startling array of schemes to influence surgeons," including compensation for joining a medical society created by a medical device company; purchasing billboard space to advertise medical practitioners; providing employment to surgeon's relatives, and entertainment/sporting activities. The patient stakeholder group also emphasizes that "more than 600,000 American doctors lap up industry largesse . . . [mostly] through small payments that cover the cost of food, drinks, and travel to industry-sponsored events."

- **A second report** (August 2021) highlights the relationships between orthopedic makers and their sales reps, who are often called upon to provide technical support to surgeons in the operating room during surgeries. Device makers assert that having sales representatives must be present for certain procedures to ensure the proper functioning of highly complicated

surgical equipment and to make sure that the right scope of surgical tools and equipment are available. Critics, however, argue that the practice demonstrates the coziness between sales reps and physicians. The Kaiser report states that it is like "the relationship of a caddy and an avid golfer" and that "[d]uties can include lugging 20-pound sets of surgical hardware to the operating room, assuring it is sterile and knowing its specifications," even though – according to Kaiser – reps are not required to be trained medically. Critics further assert that companies are spending excessively for top sales talent, and the amount of money creates bad incentives, including failures to track injuries and pushing for unneeded surgeries. The result, according to Kaiser, is an increase in patient injuries and harm, which the stakeholder group asserts often go unreported.

- **A third report** (August 2021) places a spotlight on the issue of orthopedic surgeons taking ownership interests in private medical device companies, often referred to as PODs, including highly lucrative payments for selling and using products and as a result of larger medtech companies purchasing privately held medical device makers. Kaiser highlights the potential for incentivizing unnecessary surgeries and the negative consequences on patients. CMS has, in fact, **recently proposed updates to its Open Payments (Sunshine Act) program** to clarify requirements for physician-owned distributors to help ensure all of these payments are appropriately captured, reported, and publicly disclosed.

Should medical device makers pay attention to the Kaiser reports? Yes, especially makers of orthopedic devices. Increased interest from key patient stakeholder groups like Kaiser can only mean that others are also watching. We have not seen any let-up in the continued enforcement of the federal fraud and abuse laws against medical device companies. And as the government keeps the heat on the orthopedic industry, **companies should consider undertaking an independent, third-party compliance assessment** that addresses the following:

- Policies and practices on engaging health care providers to serve as consultants, including selection criteria, evaluation of payments, controls to limit influence, and documentation of services provided, focusing on royalties, speaker fees (see **OIG's November 2020 Special Fraud Alert on Speaker Programs**), and payments for technical training, among others.

- Policies and practices on physician ownership, including whether there are appropriate controls and measures for assessing when it is appropriate to provide ownership interests to physicians, especially given CMS's recent ramp-up of interest in physician-owned distributorships.

- Policies and practices relating to sales representatives in the operating room to support procedures, including identifying the extent to which videoconferencing and other virtual technologies might be used instead of permitting a rep's in-person presence in the operating room.

- Policies and practices on disclosure of payments and transfers of value made to physicians and other healthcare practitioners (as required under the Sunshine Act) and conflicts of interest, as these concerns are central to the criticisms lobbed by Kaiser and by the government in its enforcement actions.

A periodic, independent review of compliance practices helps ensure better alignment not only with federal healthcare fraud and abuse laws but also with compliance best practices and ethical principles that prioritize and protect patients. If you have any questions, please contact Matt Wetzel

(**mwetzel@goodwinlaw.com**) or (202-346-4208).

PhRMA Issues Updates to Longstanding Code, Addresses OIG's Speaker Program Guidance

PhRMA, the pharmaceutical manufacturer trade association, **announced on Fri. August 6** that it has revised its **longstanding Code on Interactions with Health Care Professionals**. The revisions, which relate to the Code's treatment of speaker programs, track concerns in a **Special Fraud Alert** released late last year by the US Department of Health and Human Services Office of Inspector General. This alert criticized the drug and medical device industry practice of engaging healthcare providers to deliver educational content to potential customers or users of products through so-called "speaker programs." The OIG found in its report that speakers were selected based on past or anticipated business; that attendees of these programs were offered remuneration in the form of lavish meals and alcohol; that programs were often held in high-end locations, often without an agenda, and often without any educational content delivered at all. The OIG also noted its findings that attendees of speaker programs regularly attend the same program more than once, calling into question their educational value. The alert expressly notes OIG's "skepticism" about such programs.

PhRMA appears to be the first of the major medical products trade associations to update its code of ethics based on the OIG's November 2020 alert. The PhRMA Code revisions from August 6 appear to address the criticisms raised by OIG. PhRMA expands its section 7 discussion of Speaker Programs, emphasizing the importance of speaker programs as a real and legitimate avenue of educating customers and product users about the benefits, risks, and science of particular products. Among the revisions:

- The PhRMA Code reiterates that incidental meals of modest value may still be offered to attendees but that they should be subordinate in focus to the educational presentation. The revisions also make it clear that companies should not pay for or provide alcohol at a speaker program, one of the OIG's chief complaints in the November 2020 alert.
- The revisions make clear that the purpose of any speaker program must be to present substantive educational information designed to help address a bona fide educational need among attendees, and that only those with a bona fide educational need should be invited. The revisions also highlight that repeat attendance at a program on the same or substantially same topic is generally not appropriate unless there is a bona fide educational need for the additional information.
- PhRMA emphasizes that the venue should be conducive to informational communication – no

extravagant venues, luxury resorts, high-end restaurants, or entertainment/sporting venues.
- Further, the PhRMA Code also spotlights the fact that speakers should be engaged following the guidelines for engaging consultants as described in the PhRMA Code – including selection based on expertise and professional qualifications rather than past or anticipated business.

Revisions to the new PhRMA Code become effective January 1, 2022. This gives companies just a few months to evaluate their compliance policies and to update messaging to their employees regarding the appropriate set-up and operation of speaker programs, if any revisions to current practices are required.

If you have questions about this update, please contact Matt Wetzel (**mwetzel@goodwinlaw.com**, (202) 346-4208).