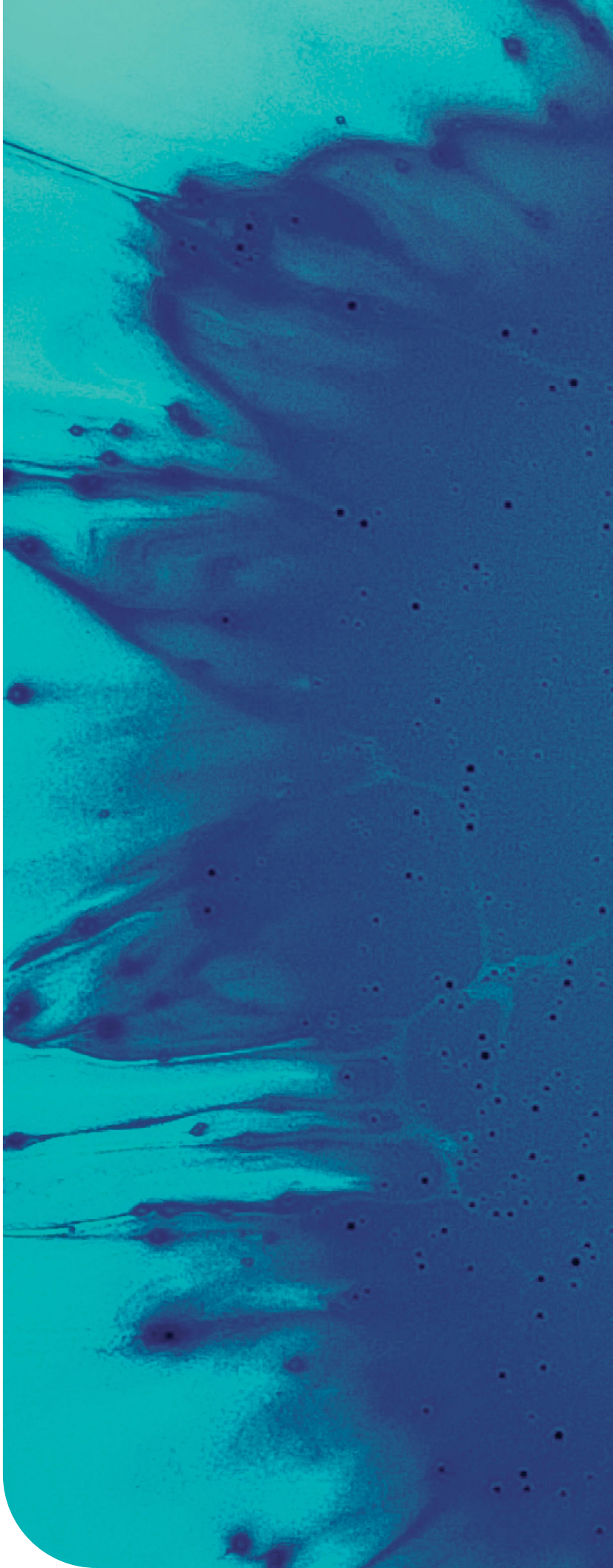
PORZIO
Life Sciences

Practical Compliance Guidance:

Key Learnings for DOJ Updates, OIG Fraud Alert and Open Payments Enforcement Action



In this compilation, Porzio Life Sciences provides recent updates from Porzio Compliance Digest highlighting the latest information on DOJ Updates, Fraud Alerts and Open Payments Enforcement Actions.

June 29, 2021

Sentencing Continues for MDs Taking Kickbacks From Insys

Jeffrey Goldstein, a former Manhattan osteopathic doctor, was recently sentenced to 57 months in prison for conspiring to violate the Anti-Kickback Statute by taking hundreds of thousands of dollars in kickbacks through speaker program fees and in connection with other areas of value from Insys Therapeutics Inc. ("Insys") in return for prescribing large volumes of Subsys fentanyl spray to his patients.

In 2019, Jeffrey Goldstein pled guilty in U.S. District Court, to accepting kickbacks from Insys from 2013 to 2015. According to the complaint, in 2012 Insys established a Speakers Bureau consisting of doctors selected and compensated by Insys to provide educational presentations regarding Subsys, but in reality, the speaker programs were social gatherings at high end restaurants where doctors were not provided educational presentations, and were encouraged to prescribe large volumes of the drug.

In Goldstein's sentencing submission, provided prior to the Department of Justice Press Release indicating the doctor's sentencing, his attorneys noted the hardships his family experienced after loss of his medical license, and stressed Goldstein's conduct during the COVID-19 crisis. Goldstein worked with Sollis Healthcare (a medical clinic in NYC) to administer COVID-19 tests, as a technician, not a doctor. Goldstein also volunteered for the American Red Cross in April 2020, and although denied, Goldstein signed up to join the Committee for Physician Health.

Other doctors, Gordon Freedman, Alexandru Burducea, Todd Schlifstein and Dialecti Voudouris were also convicted and charged alongside Goldstein in 2018 some of which included time in prison as well. Freedman was convicted at trial and his sentencing is scheduled for July.

The case is U.S. v. Freedman et al., case number 1:18-cr-00217, in the U.S. District Court for the Southern District of New York.

In 2019 Insys agreed to settle Federal criminal and civil charges including payment of kickbacks and illegal marketing practices and paid $225 million in penalties, resulting in the company seeking Chapter 11 protection.

July 14, 2021

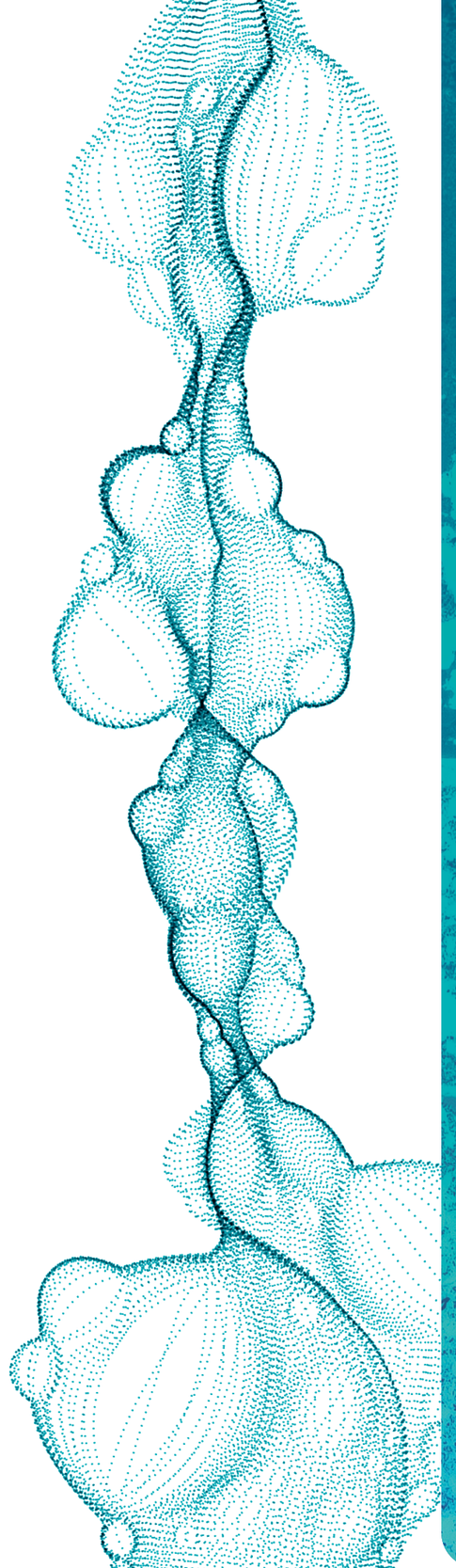
Medical Device Companies Agree to Pay $38.75 Million to Settle FCA Allegations

According to a recent Department of Justice (DOJ) News Release, Alere Inc. and Alere San Diego, Inc. (collectively "Alere") have agreed to pay $38.75 million to resolve allegations that the companies violated the False Claims Act. Both companies manufacture and sell INRatio blood coagulation monitors that are essential to determine a clinically appropriate and safe dosage for anticoagulant medications. The monitors consist of a reusable meter and disposable test scripts.

The government alleges that, from 2008 to 2016, Alere knowingly provided INRatio blood coagulation monitors that contained a material defect in the software algorithm used. It was further alleged that Alere knew that patients and healthcare providers relied on INRatio's results in making healthcare decisions. Alere's own personnel appeared to repeatedly warn the company that the algorithm could return discrepant results. The government notes that Alere was aware of the "system limitation" that contributed to over a dozen deaths and hundreds of injuries, including intra-cerebral hemorrhaging and cardiovascular events following bleeding episodes. According to the settlement, "despite knowing of the INRatio defect, Alere continued to distribute and sell INRatio systems." The devices were ultimately removed from the market in 2016, at the request of the U.S. Food and Drug Administration (FDA), via a nationwide Class I product recall.

The U.S. also alleges that the companies knowingly submitted or caused to be submitted false claims to Medicare for defective testing devices. "If Alere had properly disclosed INRatio's defect, Medicare would not have paid those claims, which were for the use of an INRatio system that was neither reasonable and necessary, nor safe and effective."

Acting Assistant Attorney General Brian M. Boynton of the Justice Department's Civil Division states in the News Release, "Patients and health care providers rely on diagnostic devices to provide reliable health information. The Department of Justice will hold accountable medical device companies that knowingly sell defective products that can harm patients and waste taxpayer dollars."



August 11, 2021

PhRMA Updates Code on Interactions With Health Care Professionals

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a trade group representing companies in the pharmaceutical industry in the United States. Last week PhRMA issued an updated and enhanced "Code on Interactions With Health Care Professionals." The updated Code takes effect on January 1, 2022. The Code is similar to the previous version, which was revised in September 2019, with some key differences regarding Speaker events and meals provided to HCPs, and also appears to align with the recent OIG Speaker Program Fraud Alert ("OIG Alert").

The most extensive changes to the Code are in Section 7/Speaker Programs and Speaker Training Meetings. Several guidelines were added to this section, including what the purpose of speaker programs should be, and that invitees should have a bona fide need for attending, companies should not pay for or provide alcohol, company representatives should be physically present at speaker programs, and venues should not be luxury resorts or high-end restaurants. The updated Code also notes that repeat attendance on the same/substantially same topic is generally not appropriate unless there is a bona fide educational need, and attendance by speakers as participants at programs after speaking on the same topic is generally not appropriate.

Section 2/Informational Presentations by Pharmaceutical Company Representatives and Accompanying Meals remained mainly unchanged except for a statement that notes "Incidental meals can be provided only where there is a reasonable expectation, and reasonable steps are taken to confirm, that each attendee has a substantive interaction or discussion with the company representative. Offering "grab-and-go" meals is not appropriate."

The Code refers to meals provided to HCPs in multiple sections, and when referenced, often includes the term "incidental" in the description, although "incidental" is not defined within the Code.

Additional language was added to some sections taking into consideration events that may be "virtual" and in person, such as CME events, third-party scientific and educational conferences or professional meetings.

When discussing the use of HCPs as consultants or speakers, the Code consistently notes that companies "should not take into account the volume or value of past business that may have been or potential future business that could be generated for the company by the health care professional consultant."

The Question & Answer section was also updated based upon the above referenced additions. For example, Q7 discusses company representatives or immediate managers conducting presentations/discussions with an occasional meal in the office or hospital setting, whereby the answer included that "an incidental meal can be provided only where there is a reasonable expectation, and reasonable steps are taken to confirm, that each attendee receiving a meal has a substantive interaction or discussion with the company representative. Offering "grab-and-go" meals is not appropriate."

According to PhRMA, the Code "is to reinforce our intention that our interactions with health care professionals are professional exchanges designed to benefit patients and to enhance the practice of medicine."

August 02, 2021

Centers for Medicare and Medicaid Services Proposes Clarifying Revisions to Reporting Rules for Open Payments Program

The Centers for Medicare and Medicaid Services ("CMS") has proposed revisions to its Open Payments regulations that would be effective for data collected in calendar year 2023 and reported in calendar year 2024. The proposed revisions would clarify existing reporting requirements and improve the quality of the data reported.

Among other things, the proposed rules would revise current requirements in the following ways:

- Add a mandatory context field for transfers of value to teaching hospitals in order to better identify payment information;
- Allow a reporting entity to delete a record only if the information is found to be incorrect or meets existing exceptions;
- Include a specific definition of physician-owned distributorship ("POD") as a subset of either an applicable manufacturer or group purchasing organization ("GPO") and require PODs to self-identify when registering or recertifying;
- Provide for optional annual recertification to allow reporting entities to attest that they do not have any reportable records for a reporting year.
- Eliminate an entity's ability to delay publication of general payments;
- Clarify that a 90-day short term loan of a medical supply or device means the loan is not to exceed 90 cumulative days per calendar year;
- Remove the "Ownership" Nature of Payment category; and
- Make it mandatory for companies to update their contact information in the Open Payments System.

Interested stakeholders may submit written comments until September 13, 2021, and should include the file code CMS-1751-P.

June 23, 2021

Telehealth Companies Face Kickback Charges

At the February 2021 Federal Bar Association Qui Tam Conference, Acting Assistant Attorney General Brian M. Boynton remarked, "I also expect a continued focus on telehealth schemes, particularly given the expansion of telehealth during the pandemic. Telehealth services can be a vitally important means of reaching underserved communities as well as a way to safely deliver healthcare services in the current environment." See February 25th PorzioLS EA Update.

It seems Department of Justice (DOJ) is doing just that. In a recent DOJ News release, the DOJ charged the owners of four orthotic brace suppliers and several marketing companies with allegedly organizing a nationwide kickback scheme to defraud Medicare, Tricare, Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA), and other federal and private health care benefit programs. The agency alleges that from October 2017 to April 2019, the defendants allegedly paid and received illegal kickbacks in exchange for orthotic brace orders that were not medically necessary. The total loss is estimated as $65 million.

The defendants include Thomas Farese, Pat Truglia, and Dominick Gatto of Florida, owners of orthotic brace suppliers and Christopher Cirri and Nicholas DeFonte of New Jersey, owners of a fraudulent marketing company. Charges include conspiracy to commit health care fraud and health care fraud, and paying, soliciting and receiving health care kickbacks and bribes for orders of orthotic braces.

Additional allegations included the operation of marketing call centers by Trugila, Cirri and DeFonte to solicit patient beneficiaries and induce them to accept orthotic braces, regardless of whether they needed them and hiding kickbacks to the fraudulent telemedicine companies by using sham contracts and issuing invoices for "marketing" or "business process outsourcing" expenses in exchange for signing brace orders and falsely attesting to their medical necessity.

The defendants face charges that are punishable by up to 10 years in prison and a $250,000 fine, or twice the gross profit or loss caused by the offense (whichever is greater).

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