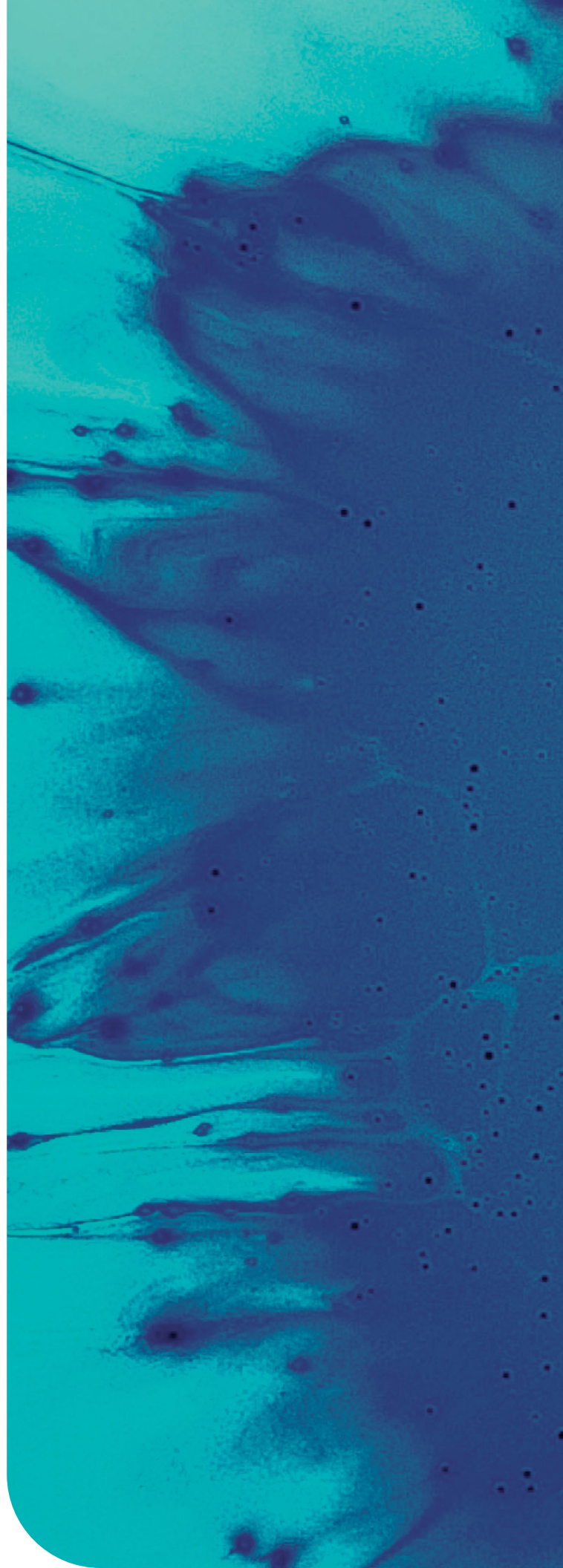




**Best Guidance  
for Managing  
Risks and Avoiding  
Enforcement Actions**



In this compilation, Porzio Life Sciences provides recent updates from Porzio Compliance Digest highlighting the latest information on Open Payments, Anti-Kickback Violations and Fraud Enforcement Actions.

October 08, 2021

## Accreditation Council for Continuing Medical Education Guidelines Go Into Effect January 2022

In January 2019, the Accreditation Council for Continuing Medical Education (ACCME) solicited feedback, in the form of a survey, from stakeholders, accredited continuing education (CE) providers, healthcare leaders, and government agencies regarding a review of the rules that protect the independence and integrity of accredited CE for healthcare professionals. Based on the feedback received, ACCME issued a draft set of Standards for Integrity and Independence in Accredited Continuing Education in January 2020, and released the final Standards in December 2020. The revised Standards will take effect on January 1, 2022, at which time all accredited providers will be expected to comply with the new or changed requirements, and can stop complying with those requirements that have been removed. ACCME will allow a one year transition phase before measuring compliance with the revised Standards.

The Standards, which were first adopted in 1992 and later updated in 2004, reflect a dedication to quality education, and aim to remain relevant and effective in the healthcare environment. In light of the updates, ACCME has published a Standards Information Package, outlining key changes to the Standards including extension of the disclosure period from 12 months to 24 months, removal of the requirement to disclose the financial relationships of spouses or partners, due to potential privacy challenges, and removal of a proposed requirement prohibiting joint providers from reimbursing expenses to faculty. In addition, with regard to accredited activities and marketing or nonaccredited activities held in the same educational space, the time interval is now defined to 30 minutes. The Standards Information Package also includes a "New Standards at a Glance" section that describes the differences between the revised and former Standards. In addition to the Standards Information Package, ACCME has also published a New Standards Standalone Package.

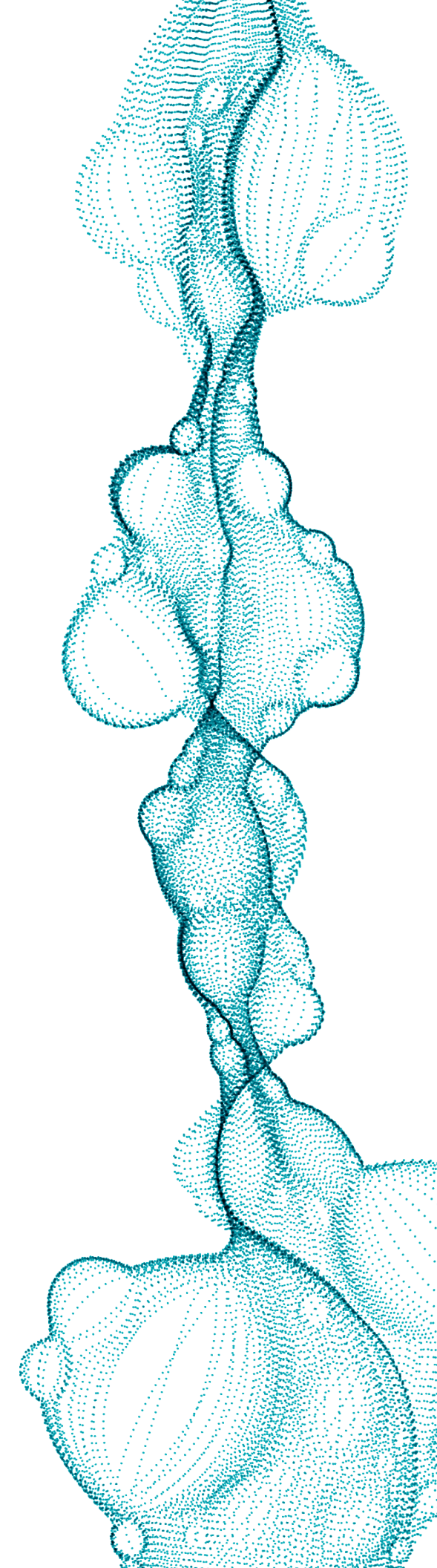
ACCME notes that "the goal of the revision process was to streamline, clarify, and modernize the Standards, and ensure their continued relevance and effectiveness in the changing healthcare environment."

October 07, 2021

## Centers for Medicare and Medicaid Services Has Posted On Its Open Payments Website The 2022 List Of Teaching Hospitals

The Centers for Medicare and Medicaid Services ("CMS") has posted on its Open Payments website the 2022 Teaching Hospital List ("List"). The final regulations implementing the Sunshine Act define a "teaching hospital" as "any institution that received a payment under 1886(d)(5)(B), 1886(h), or 1886(s) of the Act during the last calendar year for which such information is available." In order to assist applicable manufacturers in identifying teaching hospitals, CMS stated that it will publish a list of the relevant teaching hospitals "at least 90 days before the beginning of the reporting year...".

The 2022 List includes the same information categories as the 2021 Teaching Hospital List: (CMS Certification Number ("CCN"), taxpayer identification number ("TIN"), teaching hospital name, PECOS legal business name, NPPES business address, etc.). Applicable manufacturers and applicable group purchasing organizations should use the List for the January 1 through December 31, 2022, data collection period, for reporting in 2023.



October 01, 2021

## Device Manufacturer and Executives Charged with Anti-Kickback Violations

In April 2020, the Department of Justice ("DOJ") filed suit against SpineFrontier, Inc. (SpineFrontier) for an alleged kickback scheme that paid spine surgeons to use the company's spinal surgical devices. The United States complaint joined two whistleblower cases filed under the False Claims Act and named related entities and high level company executives in the alleged activity.

According to a recent indictment filed in the United States District Court for the District of Massachusetts, additional kickback charges have been filed against SpineFrontier, its founder/president/director/chief executive officer, and its chief financial officer, along with the surgeons identified as their "co-conspirators." The U.S. asserts that the company and executives paid millions of dollars in bribes to surgeons for using the company's products through a sham consulting program whereby the surgeons allegedly performed only some, if any at all, consulting work. The indictments include conspiracy to violate the Anti-Kickback Statute, violations of the Anti-Kickback Statute and conspiracy to commit money laundering. These "bribes" as indicated in the indictment were for many of the company's products in healthcare services reimbursed by federal health care programs.

According to court documents, SpineFrontier paid approximately \$2.7 million to seven surgeons from late 2012 until June 2019, which resulted in millions of dollars' worth of product sales. Prosecutors also allege that SpineFrontier tried to evade sunshine reporting and other federal restrictions by funneling the payments through a third-party corporation, owned by the founder/president/director/chief executive officer of the company, called Impartial Medical Expert LLC.

SpineFrontier Inc., and its executives pleaded guilty to the charges.

September 29, 2021

## Department of Justice Announces National Healthcare Fraud Enforcement Action

In a recent Department of Justice ("DOJ") News Release, the agency announced a National Healthcare fraud enforcement action. As stated in the News Release, the action includes criminal charges against 138 defendants in 31 federal districts across the United States. The defendants include 42 doctors, nurses, and other licensed medical professionals. The health care fraud schemes resulted in losses of approximately \$1.4 billion. According to DOJ, the alleged charges are associated with fraud committed using telemedicine (remote technological telecommunication), fraud related to COVID-19, and substance abuse fraud connected to illegal distribution of opioids in treatment facilities and traditional health care schemes across the country.

The charges associated with telemedicine include approximately \$1.1 billion in allegedly false and fraudulent claims submitted by 43 criminal defendants in 11 judicial districts. According to court documents, durable medical equipment companies, genetic testing laboratories, and pharmacies purchased orders from telemedicine executives, that allegedly paid physicians and nurse practitioners to pay for unnecessary equipment, testing and pain medications with little or no patient interaction. The orders were purchased in exchange for illegal kickbacks that led to the false and fraudulent claims to the government. In addition, certain medical professionals billed Medicare for sham telehealth consultations that did not occur as characterized. The medical professionals allegedly purchased luxury items, including vehicles, yachts, and real estate in association with this enforcement action.

The fraud schemes involving COVID-19 included nine defendants and resulted in the submission of over \$29 million in false billings. Defendants allegedly exploited CMS policies and misrepresented patient information to submit claims to Medicare for unrelated, medically unnecessary laboratory tests. In addition, some defendants face criminal charges for alleged misuse of Provider Relief Fund monies. "The Provider Relief Fund is part of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, a federal law enacted March 2020 designed to provide needed medical care to Americans suffering from COVID-19."

Additional charges involve fraudulent claims for tests and treatment for patients seeking treatment for drug and alcohol addiction in sober homes, cases involving the illegal prescription and/or distribution of opioids, and traditional health care fraud schemes.



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