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Anti-Kickback Statute Enforcement Year in Review and Outlook for 2021

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I. Introduction

While 2020 was a year like no other in many ways, the challenges posed by the global COVID-19 pandemic do not appear to have stalled the Department of Justice's (DOJ) health care fraud enforcement activities. Indeed, in fiscal year 2020, DOJ recovered more than $2.2 billion in False Claims Act (FCA) cases, with $1.8 billion of that amount coming from the health care industry.[i] Moreover, a deeper dive into those numbers reflects that a significant portion of that amount resulted from cases predicated on violations of the Anti-Kickback Statute (AKS).

While the $2.2 billion recovered last year did not break department FCA records — and was, in fact, the smallest recovery since 2008[ii] — 2020 was still a notable year in FCA and AKS enforcement in many respects. From the continued enforcement of health care provider (HCP) speaker programs to DOJ's ongoing focus on opioid manufacturers, and more novel applications of the AKS in the context of electronic health record vendors, DOJ's activity in 2020 has laid the groundwork for a number of areas to watch in 2021.

Table of Contents

III. Conclusion

II. Areas of AKS Enforcement

A. SPEAKER PROGRAMS

Without a doubt, HCP speaker programs remained one of the most significant areas of AKS enforcement and *qui tam* litigation in 2020. Last year saw a record-breaking criminal and civil resolution that, among other things, involved allegations that an opioid manufacturer used speaker payments to induce health care professionals to prescribe its products.[iii] It also saw the sentencing of an opioid manufacturer's executives based on allegations of sham speaker programs to disguise kickbacks and new charges filed against its former employees and prescribers.[iv]

Given DOJ's continued emphasis on speaker programs, and in particular allegations that speaker programs are simply a means to induce pharmaceutical prescribers, the most notable development of 2020 may have been the Department of Health and Human Services (HHS) Office of Inspector General's (OIG) signals — first hinted at in a July Corporate Integrity Agreement (CIA),[v] and then outlined in its November 16, 2020 Special Fraud Alert[vi] — as to its concerns about inappropriate speaker programs and characteristics of suspect speaker programs going forward.

Importantly, speaker programs are not, and never have been considered, *per se*, unlawful kickbacks, and OIG acknowledges as much. But, in the Special Fraud Alert, OIG identifies "significant concerns about companies offering or paying remuneration (and HCPs soliciting or receiving remuneration) in connection with speaker programs." OIG observes that many companies have halted in-person speaker programs due to the pandemic and warns that resuming such programs will result in increased risk. This warning appears to be directed to all parties associated with speaker programs, including manufacturers, HCP speakers, and HCP attendees.

The Special Fraud Alert provides a non-exhaustive list of factors related to speaker programs that OIG has identified as individually, and collectively, suspect. These include:

- The company sponsors speaker programs where little or no substantive information is actually presented;
- Alcohol is available or a meal exceeding modest value is provided to the attendees of the program (the concern is heightened when the alcohol is free);
- The program is held at a location that is not conducive to the exchange of educational information (*e.g.*, restaurants or entertainment or sports venues);
- The company sponsors a large number of programs on the same or substantially the same topic or product, especially in situations involving no recent substantive change in relevant information;
- There has been a significant period of time with no new medical or scientific information nor a new FDA-approved or cleared indication for the product;
- HCPs attend programs on the same or substantially the same topics more than once (as either a repeat attendee or as an attendee after being a speaker on the same or substantially the same topic);
- Attendees include individuals who don't have a legitimate business reason to attend the program, including, for example, friends, significant others, or family members of the HCP speaker or attendee; employees or medical professionals who are members of the speaker's own medical practice; staff of facilities for which the speaker is a medical director; and other individuals with no use for the information;
- The company's sales or marketing business units influence the selection of speaker, or the company selects

HCP speakers or attendees based on past or expected revenue that the speaker or attendees have or will generate by prescribing or ordering the company's products (*e.g.*, a return-on-investment analysis is considered in identifying participants); and

- The company pays HCP speakers more than fair market value for the speaking service or pays compensation that takes into account the volume or value of past business generated or potential future business generated by the HCPs.

As expressed in the Special Fraud Alert, OIG's skepticism about the educational value of speaker programs stems from investigations that have revealed that in many cases, HCPs have received compensation to speak at programs in circumstances that are not conducive to learning, or to speak to audience members who have no legitimate reason to attend — suggesting that the purpose of the remuneration was not educational, but rather to induce or reward referrals. OIG also posits that there are many ways for HCPs to obtain information about products and disease states that do not involve remuneration, which further suggests that, from OIG's perspective, at least one purpose of the remuneration is to induce or reward referrals.

Ultimately, the Special Fraud Alert expresses OIG's "significant concerns" about companies offering or paying, as well as HCPs soliciting or receiving, remuneration related to speaker programs. OIG further takes stock of the changes that have necessarily happened as a result of COVID-19 and suggests that, going forward, the risks associated with speaker programs will become "even more pronounced" if companies resume in-person speaker programs. More notably, OIG attempts to draw a line in the sand with respect to the amount of remuneration paid to speakers by stating that the risks will become more pronounced if companies increase speaker program-related remuneration to HCPs going forward.

No doubt, the Special Fraud Alert marks a significant shift in the enforcement landscape as several of OIG's non-exhaustive factors are squarely at odds with longstanding industry codes and norms.[vii] For decades, the PhRMA and AdvaMed Codes have served as critical guidance for industry and HCP interactions, and both of these codes provide appropriate safeguards for which manufacturers may conduct speaker programs in restaurants and provide food and beverage to attendees.

Perhaps most significantly with respect to the future enforcement landscape, OIG's focus on the involvement of sales and marketing in speaker selection, and on companies' calculation of its return on investment in speaker programs, is fundamentally at odds with the fact that these programs are, at least in part, *promotional* in nature. While we have seen examples of enforcement actions focus on the involvement of sales and marketing in certain company initiatives (for example, the copay assistance cases discussed *infra*), never before has OIG suggested the exclusion of sales and marketing from activities that are squarely within its domain.

So, what are manufacturers to do? This will no doubt be a pressing question for in-house counsel and compliance officers as pandemic restrictions eventually ease and the world strives to return to "normal." While the Special Fraud Alert signals heightened risk around, and increased enforcement focus on, speaker programs, as with any AKS risk, the actual issue is one of intent. OIG acknowledges that no one factor is determinative of an AKS violation. To that end, companies should evaluate their speaker programs against the factors outlined in the Special Fraud Alert and consider whether the frequency, location, attendees, content, or remuneration associated with these programs reflects an intent to induce or reward prescriptions. Manufacturers who elect to conduct programs — whether live or virtual — should take stock of their rationale for conducting programs, and continually reassess whether circumstances change such that continued programs are no longer necessary for any particular

product or territory. Manufacturers should also monitor the content, attendees, and expenses associated with their programs to ensure compliance — and document all of the above. As noted in the Special Fraud Alert, manufacturers may also, of course, seek an advisory opinion to have more certainty as to the risks associated with their speaker programs.

B. TELEMEDICINE

One area of increased AKS enforcement likely to come out of the COVID-19 pandemic is telemedicine — that is, the use of telecommunications technology to provide health care services to patients remotely.

Until recently, the use of telemedicine was minimal in the United States, and Medicare-reimbursable telemedicine services were relatively limited. But in March 2020, in response to the COVID-19 pandemic, CMS and other insurers relaxed the requirements for reimbursement. Understandably, the use of telemedicine services has soared, as it allows patients to receive health care from the safety of their homes. Indeed, CMS reported that in April 2020, nearly half (43.5% or 1.28 million per week) of Medicare primary care visits were conducted via telemedicine compared to just 0.1% in February.[viii] And there are signs that patients and health care providers have little interest in returning to the pre-COVID-19 status quo. The global telemedicine market — valued at $38.7 billion in 2020 — is projected to reach $191.7 billion by 2025.[ix]

In October 2020, DOJ's Operation Rubber Stamp (conducted on the heels of two nationwide telemedicine takedowns in 2019) resulted in charges against 86 defendants in 19 judicial districts and alleged a $4.5 billion fraud loss related to nationwide telemedicine kickback schemes.[x] Although the takedown stemmed from conduct that occurred long before COVID-19, it suggests that DOJ is laser-focused on this growing facet of the health care industry and will continue to be as telemedicine services expand.

Notably, however, the telemedicine schemes alleged in Operation Rubber Stamp are not novel "telemedicine" schemes at all. They are traditional self-referral kickback schemes executed, in part, via telemedicine. In Operation Rubber Stamp, patients allegedly were lured into the scheme by a telemarketing network, and telemedicine provider defendants allegedly paid doctors and nurse practitioners to order unnecessary DME, genetic and other diagnostic testing, and pain medications — without any interaction with the patients or with only a brief telephonic conversation with the patients, whom they had never met or seen before.

While self-referral schemes present AKS risks to telemedicine companies — as they do in all facets of health care — for telemedicine providers, Operation Rubber Stamp and other telemedicine AKS takedowns should not overshadow other significant False Claims Act risks more closely associated with the provision of telemedicine services. These include upcoding, misrepresenting virtual services provided, and billing for virtual services not provided. As telemedicine services expand, providers should be attuned to the rapidly evolving regulatory environment and sharpen their focus on compliance.

C. COPAY ASSISTANCE

Not surprisingly, donations to copay assistance foundations continued to be a key AKS enforcement theme in 2020. Four manufacturers,[xi] one charity,[xii] and one specialty pharmacy[xiii] entered into civil settlements with the District of Massachusetts, resolving allegations of their involvement in using copay assistance foundations as conduits to pay kickbacks to Medicare beneficiaries. With 18 total settlements between 2017 and 2020 totaling

over a billion dollars, these resolutions signal what is likely soon to be the end of DOJ's industrywide investigation that charted new territory in AKS enforcement.

While DOJ's investigations into copay assistance are seemingly coming to an end, litigation on the issue is just beginning. Indeed, in 2020, DOJ filed civil complaints against three manufacturers alleging that pharmaceutical manufacturers' donations to copay assistance foundations were unlawful kickbacks intended to induce prescriptions of the manufacturers' products. In two of those cases, courts have already denied defendants' motions to dismiss,[xiv] and a motion to dismiss is pending in the third.[xv] Relatedly, a fourth manufacturer has a pending motion for summary judgment in a *qui tam* suit in which the government has filed a statement of interest.[xvi] In each of these cases, defendant-manufacturers universally assert that (1) the independence between the defendants and the copay assistance foundations breaks the chain of causation between a donation and a potential kickback, and (2) the distinction between a "hope or expectation" that a donation would result in increased prescriptions and an "intent to induce." These cases will surely be ones to watch closely in 2021.

On a similar track, after settling its own copay assistance investigation in 2018, Pfizer sued HHS in June 2020 seeking a declaratory judgment that patient assistance programs for two of its specialty drugs, which would involve donations to copay assistance foundations and copay cards, are legal.[xvii] Pfizer's complaint alleges that the agency's incorrect interpretation of the AKS and the Beneficiary Inducement Statute has prevented, and continues to prevent, patients from accessing medications. The complaint alleges that OIG has imposed "severe restrictions on a pharmaceutical manufacturer's communications with and donations to independent charities that impede the manufacturer's ability to bestow a meaningful and effective gift by, for example, ensuring the charity has sufficient funds to cover all patients who require assistance accessing treatment or medication." The resulting harm, as alleged in the complaint, is an infringement of Pfizer's First Amendment rights, as well as a substantial negative impact on patient care. The complaint describes the company's intent as seeking to ensure that patients receive necessary medical treatment, rather than "corrupt[ing]" physicians into prescribing its drugs.

On another front, in September 2020, OIG released Advisory Opinion 20-05 rejecting a manufacturer's (Requestor) proposal to provide cost-sharing assistance directly to Medicare beneficiaries. Advisory Opinion 20-05 addressed in great detail the Requestor's proposal to institute a cost-sharing assistance program for qualified Medicare beneficiaries who are prescribed the manufacturer's medication — currently priced at $225,000 for a one-year course of treatment (and described by OIG as the most expensive medication launched in the United States). Drawing on the settlements in the copay assistance investigation, OIG noted its concern that pharmaceutical manufacturers blunt the impact of patient cost sharing to induce patients to fill prescriptions for costly medications, which removes "potential downward pressure on the price of the drugs."

Advisory Opinion 20-05 explains that the Requestor certified that the beneficiary cost-sharing obligation for the drug is approximately $13,000 per year — an impediment to most Medicare beneficiaries. In concluding that the arrangement was "highly suspect" under the AKS, OIG explained that because the beneficiary would know about the availability of the subsidy when deciding whether to fill their prescription, "the subsidy card would be offered to beneficiaries to induce them to purchase a covered item by removing what would otherwise be an impediment that would deter such a purchase." Moreover, even though the Requestor represented that its medication was the only approved treatment for the disease state and, as such, offering copay assistance to help eligible patients afford a clinically-appropriate medication did not improperly induce the underlying prescribing decision, OIG reasoned that because one purpose of the remuneration would induce the beneficiary to *purchase the medication*, the

arrangement was inherently suspect under the AKS.

OIG has explained that cost sharing is a critical element of the Medicare program because it encourages patients to make rational decisions when there are lower-cost, appropriate, therapeutic alternatives. But here, the Requestor makes a persuasive argument that when the underlying decision to prescribe a medication is independent and untainted, and the medication is the *only* treatment option, cost sharing does not discourage rational decision-making, but rather serves as the sole barrier to access for financially needy Medicare beneficiaries. Thus, Advisory Opinion 20-05's ultimate conclusion is in seeming contradiction to OIG and the industry's shared goal of "ensuring that beneficiaries who enroll in Medicare Part D have access to medically necessary drugs." The ongoing litigation in this space will undoubtedly be an area of continued activity in 2021 as OIG and DOJ continue to take an aggressive position on all fronts.

D. ELECTRONIC HEALTH RECORDS (EHR)

In recent years, DOJ has expanded its theories of liability under the AKS to include indirect relationships between both manufacturers and patients/beneficiaries and manufacturers and prescribers (indeed, the copay assistance investigations are just one example). Following this trend toward expansion, DOJ has also begun to scrutinize EHR vendors and their relationships with manufacturers.

In January 2020, DOJ announced that Practice Fusion, an EHR vendor, agreed to pay $145,000,000 to resolve criminal and civil allegations that it solicited and received kickbacks from pharmaceutical companies in exchange for implementing clinical decision support (CDS) alerts in its EHR software to increase prescriptions for the pharmaceutical companies' products. Practice Fusion executed a deferred prosecution agreement and admitted that it solicited and received kickbacks from a major opioid company (later identified as Purdue Pharma LP), in exchange for utilizing its EHR software to influence physicians prescribing opioid pain medications. Practice Fusion also entered into a civil settlement agreement to resolve allegations that it misrepresented its software's compliance with applicable requirements, thereby causing health care providers to falsely attest to compliance with CMS requirements necessary to receive EHR-based incentive payments; and that it accepted kickbacks from the opioid company and other pharmaceutical companies, thereby causing health care providers to submit false claims for kickback-tainted prescriptions.[xviii]

Relatedly, as part of its $2,800,000,000 global opioid resolution, Purdue settled allegations that it paid kickbacks to Practice Fusion in exchange for implementing clinical decision support alerts to increase the prescribing of opioid medications.[xix]

The seeming novelty of the theory of AKS liability articulated in the Practice Fusion and Purdue complaints is that in between the CDS alert in the EHR software, and the ultimate prescription to a patient, is an HCP who makes the independent clinical decision to prescribe the drug based on his/her own professional medical judgment. The HCP is unaware of the purported improper payment by a manufacturer (Purdue) to a third party (Practice Fusion) to induce the prescription. This apparent break in the chain of alleged kickback causation should provide a defense to allegations of liability. But, the Practice Fusion and Purdue complaints go further to allege that the clinical guidelines in the Purdue-sponsored CDS were inaccurate and therefore improperly influenced the prescribing physician's medical judgment.

It remains to be seen whether and how this theory will apply to pharmaceutical companies that collaborated with

EHR vendors on CDS alerts where the clinical decision support provided was *clinically appropriate* and resulted in *proper medical treatment* that does not raise quality of care or patient safety concerns.

While not legally binding outside the Practice Fusion resolution, the compliance addendum executed as part of Practice Fusion's deferred prosecution agreement informs DOJ's current views on how sponsored CDS alerts should be executed.[xx] These attributes include the following:

- The CDS is medically accurate and appropriate, based on "medical review" and "consultation with medical professionals with expertise in the area of medicine . . . at issue";
- The CDS is "commercially neutral" and is "not influenced or directed by" a sponsor's own commercial interests;
- The sponsor's sales, marketing, and brand personnel are not involved, either directly or indirectly, in the design or creation of the CDS;
- The sponsor's sales, marketing, and brand personnel are not involved in financing the CDS; and
- The CDS must be neither marketed or sold based on a sponsor's anticipated return on investment or increase in sales, nor contingently funded based on an actual return on investment or increase in sales.

Manufacturers should take note of these characteristics, as in February 2020, the assistant attorney general for DOJ's Civil Division noted "the critical and growing role that electronic health records play in our health care system today" and predicted "more of these cases in the future."[xxi]

E. SELF-REFERRALS

Another area of continued enforcement in 2020 were cases focused on physician self-referrals, or the offering and/or receipt of improper payments to physicians for the purpose of inducing referrals. In 2020, DOJ recovered over $125,000,000 in settlements from hospitals, medical centers, laboratories, and physicians for financial arrangements that allegedly violated the AKS and Stark Law. While this has long been an area of scrutiny for DOJ, the following types of financial arrangements were the subject of enforcement actions this past year:

- Compensation to physicians for services in excess of fair market value.[xxii]
- Compensation to referring physicians in the form of excessive "draw fees" or "per specimen fees" for laboratory tests.[xxiii]
- The payment of "administrative service fees" to a laboratory customer in exchange for patient testing services.[xxiv]
- Compensation arrangements with physician employees that took into account the value of referrals for in-office laboratory tests.[xxv]

The takeaway from these enforcement actions is that DOJ is continuing to scrutinize financial relationships between and among referral sources. A best practice for such financial arrangements is to structure them to fit within the safe harbors under the AKS and the Stark Law, including by ensuring that any compensation or remuneration represents fair market value for the services offered or provided.

F. PRACTICE BUILDING AND SUPPORT

In addition to patient inducements, another continued focus for AKS enforcement is remuneration provided to physicians and practices in exchange for practice building and practice support. In 2020, DOJ recovered at least

$30,000,000 in settlements from medical device manufacturers and biotechnology companies that allegedly provided support to physician practices and hospitals that were intended to induce or reward use of their products. The types of conduct that DOJ pursued in these actions include the following:

- A medical device manufacturer settled allegations that it provided physicians, medical practices, and hospitals with free advertising assistance, practice development, practice support, and purported educational grants to induce the purchase and use of its products in medical procedures.[xxvi]
- A biotechnology settled allegations that it partially subsidized the cost of electronic medical records software for physicians' offices based on the volume of business those practices generated.[xxvii]

Neither of these fact patterns involved novel applications of the AKS. Yet, this will remain an active area for DOJ enforcement and potential *qui tam* complaints. It further demonstrates DOJ's particular concern around the independent judgment of HCPs, as well as the competitive marketplace, being distorted or compromised by improper financial incentives.

This is not to suggest that legitimate support programs for physicians and their patients (such as reimbursement support, patient education, and nursing services, to name a few) can *never* be consistent with federal health care program interests. Indeed, not every financial transaction that poses potential AKS risk constitutes a *per se* unlawful kickback.[xxviii] But given the breadth of the AKS, it is of paramount importance to consult with in-house or outside counsel — or even request an OIG advisory opinion — before undertaking such a program. This is because the program must be carefully structured to reduce the risk that DOJ, a court, or an administrative agency might conclude that at least one of the remunerations is to induce referrals of federal health care program business. And while AKS liability ultimately depends on a party's intent, there are several risk-mitigating considerations that can be useful when scrutinizing a contemplated support program. These considerations include, for example, whether the program will interfere with or skew independent clinical decision-making; increase the risk of overutilization or inappropriate utilization; increase costs to federal health care programs, beneficiaries, or enrollees; implicate patient safety or quality of care concerns; or confer substantial independent value or value that is not integrally related to the product or service.[xxix]

Any company or individual considering a practice support program should exercise caution and pay close attention to this broad framework in designing, implementing, and monitoring to minimize their enforcement risk.

G. CONSULTING PAYMENTS, GIFTS, AND MEALS

Remuneration provided to physicians in the form of consulting payments, gift cards, and meals remains — and will continue to be — a focus of AKS enforcement efforts. In 2020, DOJ recovered approximately $34,000,000 in settlements from companies and individuals that allegedly paid or accepted kickbacks, which were intended to induce or reward the prescribing of drugs, the use of medical devices, and the ordering of tests. The types of financial transactions that DOJ pursued in these actions include, for example:

- A biotechnology testing company settled allegations that it provided meals and happy hours for physicians and their employees to induce the ordering of their tests.[xxx]
- A medical device manufacturer settled allegations that it paid for social events, including food and drinks, held at a physician-owned restaurant to induce the use of its infusion pumps.[xxxi]
- A pharmaceutical company settled allegations that it provided sham research grants to health care providers and their institutions to induce the use its analgesic during procedures.[xxxii]

- A physician assistant settled allegations that it solicited and accepted meals, gift cards, gifts, and compensation from speaking engagements, advisory boards, and consulting services from a pharmaceutical company in exchange for prescribing the company's drugs.[xxxiii]
- A vice president of a genetic testing company pleaded guilty to conspiring to pay sham clinical research fees to health care providers to induce them to order its tests.[xxxiv]

Moreover, DOJ recently intervened in two lawsuits currently before the District of Massachusetts, filed under the whistleblower provisions of the False Claims Act. The lawsuit stems from whistleblower allegations that a medical device manufacturer violated the AKS when it paid kickbacks — in the form of sham consulting fees — to spine surgeons and neurosurgeons to induce their use of its surgical devices.[xxxv] In 2020, six surgeons separately admitted to having accepted the medical device manufacturer's alleged sham consulting fees, resulting in individual settlements ranging from $105,149 up to $1,750,000.[xxxvi]

While none of the above pushed previously established boundaries of the AKS, the payment of consulting fees, gift cards, and meals undoubtedly remains a lucrative staple for DOJ enforcement and recovery efforts (and also is ripe for civil whistleblower complaints). These actions also demonstrate DOJ's continued concern around improper inducements potentially undermining a doctor's medical decision-making, steering the overutilization of certain products, and driving up costs to public health care programs.

This is not to suggest that industry can never partner with HCPs without being subject to AKS liability — the AKS's purpose is not to stifle legitimate consulting engagements and collaborative research initiatives that will improve health care delivery and patient outcomes. But certain guardrails should be constructed around such endeavors to minimize the risk that DOJ, a court, or an administrative agency might conclude that any attendant remuneration carries an unlawful or illegitimate purpose. If providing research grants, for example, the initiative should be accompanied by documentation of the proposed research, reasonable commercial need, and fair market value assessments; and after providing grants, there should be documentation that the research was performed according to the original proposal and how the research was then utilized in furtherance of the identified commercial need.

That said, continued DOJ enforcement efforts send the strong signal that companies and individuals should exercise caution and diligence when deciding whether to enter into financial transactions or partner with health care providers. Even the most seemingly trivial remuneration — down to food and drink — can potentially bear scrutiny under the AKS if tied to an inducement or referral for items or services reimbursable by federal health care programs.

III. Conclusion

While many of the areas outlined above represent the ordinary bread and butter of AKS enforcement, 2020 nonetheless brought about notable developments in the form of OIG's Special Fraud Alert relating to speaker programs, an increased emphasis on telemedicine, DOJ's novel application of the AKS to EHR vendors, and the ongoing access-to-medicine issues raised by the copay assistance cases. In addition to the change of administration, which is expected to prioritize white collar investigations and prosecutions, there is no reason to believe that AKS enforcement efforts will slow down.

[i] *See* DOJ, Press Release (Jan. 14, 2021) (announcing over $2.2 billion in recovery from False Claims Act Cases in fiscal year 2020).

[ii] *See* DOJ, Press Release (overviewing fraud statistics since 1986 and reflecting a decline in recoveries since 2014).

[iii] *See* DOJ, Press Release (Oct. 21, 2020) (announcing $8 billion global resolution of criminal and civil investigations and civil settlement). As the Purdue settlement was not finalized before the conclusion of fiscal year 2020, it was not included in DOJ's total recoveries cited above.

[iv] *See, e.g.*, DOJ, Press Release (Jan. 13, 2020) (announcing sentencing of former vice president); DOJ, Press Release (Jan. 23, 2020) (announcing sentencing of founder and former chairman); DOJ, Press Release (Jan. 27, 2020) (announcing sentencing of a doctor); DOJ, Press Release (Sept. 16, 2020) (announcing charges against a doctor).

[v] *See* HHS-OIG, Corporate Integrity Agreement (June 30, 2020).

[vi] *See* HHS-OIG, Special Fraud Alert: Speaker Programs (Nov. 16, 2020).

[vii] *See* The Pharmaceutical Research and Manufacturers of America (PhRMA), Code on Interactions with Health Care Professionals; AdvaMed, Code of Ethics on Interactions with U.S. Health Care Professionals.

[viii] *See* HHS, Issue Brief, *Medicare Beneficiary Use of Telehealth Visits: Early Data from the Start of the COVID-19 Pandemic* (July 28, 2020).

[ix] *See* PR Newswire, News Release, *The Worldwide Telehealth/Telemedicine Industry Is Estimated to Reach $191.7 Billion by 2025* (Dec. 8, 2020).

[x] *See* DOJ, Press Release, (Oct. 7, 2020) (announcing charges in connection with Operation Rubber Stamp); DOJ, Press Release (Oct. 7, 2020) (same).

[xi] *See* DOJ, Press Release (Feb. 28, 2020) (announcing $11.85 million settlement); DOJ, Press Release (July 1, 2020) (announcing $642 million settlement); DOJ, Press Release (Sept. 23, 2020) (announcing $97 million settlement); DOJ, Press Release (Dec. 17, 2020) (announcing $22 million settlement).

[xii] *See* DOJ, Press Release (Jan. 21, 2020) (announcing $3 million settlement).

[xiii] *See* DOJ, Press Release (Aug. 13, 2020) (announcing $3.5 million settlement).

[xiv] *See* No. 1:20-cv-11217 (D. Mass Dec. 4, 2020); No. 2:12-cv-00175 (E.D. Pa. Jan. 21, 2020).

[xv] *See* No 1:20-cv-11548 (D. Mass.).

[xvi] *See* No. 2:18-cv-02642 (E.D. Pa.).

[xvii] *See* No. 1:20-cv-04920 (S.D.N.Y).

[xviii] *See* DOJ, Press Release (Jan. 27, 2020) (announcing $145 million criminal and civil resolution).

[xix] *See* DOJ, Press Release (Oct. 21, 2020) (announcing $8 billion global resolution of criminal and civil investigations and civil settlement).

[xx] *See* DOJ, Compliance Addendum (Jan. 26, 2020).

[xxi] *See* Law360, Top DOJ Atty Spotlights Main FCA Target Areas for 2020 (Feb. 27, 2020).

[xxii] *See* DOJ, Press Release (Feb. 14, 2020) (announcing $4.1 million settlement); DOJ, Press Release (July 8, 2020) (announcing $72.3 million settlement).

[xxiii] *See* DOJ, Press Release (July 23, 2020) (announcing $49 million settlement); DOJ, Press Release (Oct. 2, 2020) (announcing $3 million settlement).

[xxiv] *See* DOJ, Press Release (July 20, 2020) (announcing $12 million settlement).

[xxv] *See* DOJ, Press Release (Apr. 22, 2020) (announcing $10 million settlement); DOJ, Press Release (Sept. 9, 2020 (announcing $50 million settlement).

[xxvi] *See* DOJ, Press Release (Oct. 14, 2020) (announcing $18 million settlement).

[xxvii] *See* DOJ, Press Release (Sept. 22, 2020) (announcing $11.5 million settlement).

[xxviii] *See* HHS-OIG, Advisory Opinion 20-06 (Dec. 18, 2020) (determining that, despite the potential to generate prohibited remuneration under the AKS "if the requisite intent to induce or reward referrals of Federal health care program business were present," the OIG would not prohibit a management company from providing Medicaid enrollment application assistance services to certain individuals or from receiving payments from affiliated skilled nursing facilities for those services).

[xxix] *See* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (2003); *see also* OIG Supplemental Compliance Program Guidance for Nursing Facilities, 73 Fed. Reg. 56,832, 56,843-56,844 (2008); Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute, 78 Fed. Reg. 79,202, 79,210 (2013).

[xxx] *See* DOJ, Press Release (July 23, 2020) (announcing $49 million settlement).

[xxxi] *See* DOJ, Press Release (Oct. 29, 2020) (announcing $9.2 million settlement).

[xxxii] *See* DOJ, Press Release (July 28, 2020) (announcing $3.5 million settlement).

[xxxiii] *See* DOJ, Press Release (July 10, 2020) (announcing $25,000 settlement).

[xxxiv] *See* DOJ, Press Release (Aug. 4, 2020) (announcing guilty plea of vice president).

[xxxv] *See* No. 1:15-cv-12877 (D. Mass.); No. 1:15-cv-12908 (D. Mass.).

[xxxvi] *See* DOJ, Press Release (Apr. 24, 2020) (announcing individual settlement of $1.75 million); DOJ, Press Release (Mar. 5, 2020) (announcing five settlements totaling $1.56 million).

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