Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–N–1778 for ''Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: LaToya Bonner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–2855, Fax: 301–847–8533, email: *EMDAC@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The committee will discuss new drug application (NDA) 215559, for palovarotene capsules, submitted by Ipsen Biopharmaceuticals, Inc. The proposed indication is the prevention of heterotopic ossification in adults and children (females aged 8 years and above and males 10 years and above) with fibrodysplasia ossificans progressiva.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before October 17, 2022, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. eastern time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 6, 2022. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 7, 2022.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact LaToya Bonner at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 17, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–18143 Filed 8–22–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Publication of OIG Special Fraud Alerts

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This **Federal Register** notice sets forth two Special Fraud Alerts previously published by OIG on its website. We are publishing these Special Fraud Alerts in the **Federal Register** to ensure widespread dissemination of the Special Fraud Alerts to the general public and to satisfy the **Federal Register** publication requirement.

FOR FURTHER INFORMATION CONTACT: Katie Fink, Karen Glassman, or Benjamin Wallfisch, (202) 619–0335.

I. Background

Pursuant to 42 U.S.C. 1320a–7d(c), OIG periodically issues Special Fraud Alerts to give continuing guidance to health care industry stakeholders regarding practices OIG considers to be suspect or of particular concern. Special Fraud Alerts encourage industry compliance by giving stakeholders guidance that can be applied to their own practices. In developing Special Fraud Alerts, OIG relies on several sources and consults directly with experts in the subject field including those within OIG, other HHS agencies, other Federal and State agencies, and in the health care industry.

To ensure widespread dissemination of this information to the general public and to satisfy the **Federal Register** publication requirement found in 42 U.S.C. 1320a–7d(c)(1)(B), OIG is republishing two Special Fraud Alerts—in their entirety—below. These Special Fraud Alerts are: (1) Special Fraud Alert: Speaker Programs, which was originally published on OIG's website on November 16, 2020; and (2) Special Fraud Alert: OIG Alerts Practitioners To Exercise Caution When Entering Into Arrangements With Purported Telemedicine Companies, which was originally published on OIG's website on July 20, 2022.

II. Special Fraud Alert: Speaker Programs

I. Introduction

This Special Fraud Alert highlights the fraud and abuse risks associated with the offer, payment, solicitation, or receipt of remuneration relating to speaker programs by pharmaceutical and medical device companies. For purposes of this Special Fraud Alert, speaker programs are generally defined as company-sponsored events at which a physician or other health care professional (collectively, ''HCP'') makes a speech or presentation to other HCPs about a drug or device product or a disease state on behalf of the company. The company generally pays the speaker HCP an honorarium, and often pays remuneration (for example, free meals) to the attendees. In the last three years, drug and device companies have reported paying nearly $2 billion to HCPs for speaker-related services.[1]

The Office of Inspector General (OIG) and Department of Justice (DOJ) have investigated and resolved numerous fraud cases involving allegations that remuneration offered and paid in connection with speaker programs violated the anti-kickback statute. The Federal government has pursued civil and criminal cases against companies and individual HCPs involving speaker programs. These cases alleged, for example, that drug and device companies:

- selected high-prescribing HCPs to be speakers and rewarded them with lucrative speaker deals (*e.g.,* some HCPs received hundreds of thousands of dollars for speaking); [2]
- conditioned speaker remuneration on sales targets (*e.g.,* required speaker HCPs to write a minimum number of prescriptions in order to receive the speaker honoraria);
- held speaker programs at entertainment venues or during recreational events or otherwise in a manner not conducive to an educational presentation (*e.g.,* wineries, sports stadiums, fishing trips, golf clubs, and adult entertainment facilities);
- held programs at high-end restaurants where expensive meals and alcohol were served (*e.g.,* in one case, the average food and alcohol cost per attendee was over $500); and
- invited an audience of HCP attendees who had previously attended the same program or HCPs' friends, significant others, or family members who did not have a legitimate business reason to attend the program.

Our enforcement experience demonstrates that some companies expend significant resources on speaker programs and that some HCPs receive substantial remuneration from companies. This Special Fraud Alert highlights some of the inherent fraud and abuse risks associated with the offer, payment, solicitation, or receipt of remuneration related to company-sponsored speaker programs.

II. The Anti-Kickback Statute

Congress enacted the anti-kickback statute, in part, to protect patients from referrals or recommendations by HCPs who may be influenced by inappropriate financial incentives. The anti-kickback statute makes it a criminal offense to knowingly and willfully solicit, receive, offer, or pay any remuneration to induce or reward, among other things, referrals for, or orders of, items or services reimbursable by a Federal health care program.[3] When remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. For purposes of the anti-kickback statute, the offer, payment, solicitation, or receipt of ''remuneration'' includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. By its terms, the statute ascribes criminal liability to all parties to an impermissible ''kickback'' transaction (*i.e.,* those who solicit or receive prohibited remuneration as well as those who offer or pay the prohibited remuneration). Violation of the statute is a felony punishable by a maximum fine of $100,000, imprisonment up to 10 years, or both. Criminal conviction will also lead to mandatory exclusion from Federal health care programs, including Medicare and Medicaid.[4] OIG may also initiate administrative proceedings to exclude persons from the Federal health care programs and impose civil money penalties for conduct prohibited by the anti-kickback statute.[5]

III. Fraud and Abuse Risks of Speaker Programs

Numerous investigations have involved allegations that drug and device companies organize and pay for speaker programs with the intent to

[1] Drug and device companies are required to report certain payments made to HCPs to the Centers for Medicare & Medicaid Services (CMS). CMS makes this information publicly available on its Open Payments website. According to Open Payments, drug and device companies paid HCPs nearly $2 billion under the category ''compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program'' for years 2017, 2018, and 2019 combined. *Open Payments Complete 2017, 2018, and 2019 Program Year Datasets,* CMS, *https://www.cms.gov/OpenPayments/Explore-the-Data/Data-Overview* (*accessed* Sept. 9, 2020).

[2] Though not addressed in this Special Fraud Alert, remuneration paid by drug and device companies relating to the training of HCP speakers also may raise fraud and abuse risks.

[3] See section 1128B(b)(1)–(2) of the Social Security Act; 42 U.S.C. 1320a–7b(b)(1)–(2). The anti-kickback statute applies broadly to remuneration to induce or reward referrals of patients as well as the payment of remuneration intended to induce or reward the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any item or service reimbursable by any Federal health care program. In this Special Fraud Alert, we use the term ''referral'' to include the full range of these types of activities (including ordering or prescribing items) that falls within the scope of the anti-kickback statute.

[4] See 42 U.S.C. 1320a–7(a).

[5] See 42 U.S.C. 1320a–7(b)(7); 1320a–7a(a)(7).

induce HCPs to prescribe or order (or recommend the prescription or ordering of) the companies' products. Speaker programs typically involve an HCP who is not an employee of the company speaking in person to other HCPs about a company product or disease state using a presentation developed and approved by the company. According to a pharmaceutical industry trade group, HCPs ''participate in company-sponsored speaker programs in order to help educate and inform other health care professionals about the benefits, risks, and appropriate uses of company medicines.'' [6]

OIG is skeptical about the educational value of such programs. Our investigations have revealed that, often, HCPs receive generous compensation to speak at programs offered under circumstances that are not conducive to learning or to speak to audience members who have no legitimate reason to attend. Such cases strongly suggest that one purpose of the remuneration to the HCP speaker and attendees is to induce or reward referrals. Furthermore, studies have shown that HCPs who receive remuneration from a company are more likely to prescribe or order that company's products.[7] This remuneration to HCPs may skew their clinical decision making in favor of their own and the company's financial interests, rather than the patient's best interests.

There are many other ways for HCPs to obtain information about drug and device products and disease states that do not involve remuneration to HCPs. HCPs can access the same or similar information provided in a speaker program using various online resources, the product's package insert, third-party educational conferences, medical journals, and more. The availability of this information through means that do not involve remuneration to HCPs further suggests that at least one purpose of remuneration associated with speaker programs is often to induce or reward referrals.

Parties involved in speaker programs may be subject to increased scrutiny. These include any drug or device company that organizes or pays remuneration associated with the program, any HCP who is paid to speak, and any HCP attendees who receive remuneration from the company (*e.g.,* free food and drink). OIG has long expressed concerns over the practice of drug and device companies providing anything of value to HCPs in a position to make or influence referrals to such companies' products. In the 2003 OIG Compliance Program Guidance for Pharmaceutical Manufacturers,[8] OIG identified manufacturer compensation relationships with physicians connected directly or indirectly to marketing and sales activities, including speaking activities, as an area of potential risk under the anti-kickback statute. OIG noted that when a drug or device company engages in ''entertainment, recreation, travel, meals or other benefits in association with information or marketing presentations,'' such arrangements may potentially implicate the anti-kickback statute.[9]

OIG also warned physicians that a consultant or speaking arrangement with a drug or device company could be an improper inducement ''to prescribe or use [company] products on the basis of . . . loyalty to the company or to get more money from the company, rather than because it is the best treatment for the patient.'' [10] OIG recommended that physicians consider the propriety of any proposed relationship with a company and advised that if the basis for a physician's compensation ''is your ability to prescribe a drug or use a medical device or refer your patients for particular services or supplies, the proposed consulting arrangement likely is one you should avoid as it could violate fraud and abuse laws.'' [11] Again, we note that HCPs could face liability under the anti-kickback statute for knowingly and willfully soliciting or receiving remuneration in connection with speaker programs in return for prescribing or ordering products reimbursable by a Federal health care program.

OIG recognizes that the lawfulness of any remunerative arrangement, including speaker program arrangements, under the anti-kickback statute depends on the facts and circumstances and intent of the parties. Such intent may be evidenced by the speaker program's characteristics and the actual conduct of the parties involved. Below we describe some characteristics, which, taken separately or together, potentially indicate a speaker program arrangement that could violate the anti-kickback statute. As previously stated, drug and device companies that host or pay for such speaker programs and HCPs who speak at or attend such programs could be liable under the anti-kickback statute for any prohibited remuneration. This list of suspect characteristics is illustrative, not exhaustive, and the presence or absence of any one of these factors is not determinative of whether a particular arrangement would be suspect under the anti-kickback statute.

- 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

[6] *Code on Interactions with Health Care Professionals,* PhRMA, 7 (June 2020), available at *https://phrma.org/Codes-and-guidelines/Code-on-Interactions-with-Health-Care-Professionals.* A device industry trade group also addresses this topic and interactions with HCPs generally in its code of ethics. See *AdvaMed Code of Ethics,* AdvaMed (July 2020), available at *https://www.advamed.org/resource-center/advamed-code-ethics-2020.*

[7] Amarnath Annapureddy et al., *Association Between Industry Payments to Physicians and Device Selection in ICD Implantation,* 324 *JAMA 17,* 2020, at 1759, 1762–63; William Fleischman et al., *Association between payments from manufacturers of pharmaceuticals to physicians and regional prescribing: cross sectional ecological study,* 354 BMJ i4189, 2016, at 1, 4–7; James P. Orlowski & Leon Wateska, *The effects of pharmaceutical firm enticements on physician prescribing patterns. There's no such thing as a free lunch.,* 102 Chest, 1992, 270.

[8] *OIG Compliance Program Guidance for Pharmaceutical Manufacturers,* 68 FR 23731 (May 5, 2003), available at *https://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf.* The guidance is not limited to pharmaceutical manufacturers; it states, ''the compliance program elements and potential risk areas addressed in this compliance program guidance may also have application to manufacturers of other products that may be reimbursed by [F]ederal health care programs, such as medical devices and infant nutritional products.'' Id. at 23742, n.5.

[9] Id. at 23738.

[10] *A Roadmap for New Physicians, Avoiding Medicare and Medicaid Fraud and Abuse,* HHS–OIG, 22 (Nov. 2010), *available at https://oig.hhs.gov/compliance/physician-education/roadmap_web_version.pdf; OIG Compliance Program for Individual and Small Group Physician Practices,* 65 FR 59434 (Oct. 5, 2000), available at *https://oig.hhs.gov/authorities/docs/physician.pdf.*

[11] Id. at 23.

to attend the program, including, for example, friends, significant others, or family members of the speaker or HCP 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 speakers or the company selects HCP speakers or attendees based on past or expected revenue that the speakers or attendees have or will generate by prescribing or ordering the company's product(s) (*e.g.,* a return on investment analysis is considered in identifying participants);
- 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.

IV. Conclusion

OIG has significant concerns about companies offering or paying remuneration (and HCPs soliciting or receiving remuneration) in connection with speaker programs. Based on our investigations and enforcement actions, this remuneration is often offered or paid to induce (or solicited or received in return for) ordering or prescribing items paid for by Federal health care programs. If the requisite intent is present, both the company and the HCPs may be subject to criminal, civil, and administrative enforcement actions. This Special Fraud Alert is not intended to discourage meaningful HCP training and education. Rather, the purpose of this Special Fraud Alert is to highlight certain inherent risks of remuneration related to speaker programs. Drug and device companies and HCPs should consider the risks when assessing whether to offer, pay, solicit, or receive remuneration related to speaker programs.

We are issuing this alert during the pandemic emergency, which is necessarily curtailing many in-person activities. While companies may have decreased in-person speaker program-related remuneration to HCPs during the pandemic, risks remain whenever payments are offered or made to HCPs who generate Federal health care program business for the company. The risks associated with speaker programs will become more pronounced if companies resume in-person speaker programs or increase speaker program-related remuneration to HCPs. Companies should assess the need for in-person programs given the risks associated with offering or paying related remuneration and consider alternative less-risky means for conveying information to HCPs. HCPs should likewise consider the risks of soliciting or receiving remuneration related to speaker programs given other available means to gather information relevant to providing appropriate treatment for patients. If a company or HCP has questions about a specific speaker program arrangement involving remuneration to referral sources, the OIG Advisory Opinion process remains available. Information about that process may be found at: *https://oig.hhs.gov/faqs/advisory-opinions-faq.asp.*

III. Special Fraud Alert: OIG Alerts Practitioners To Exercise Caution When Entering Into Arrangements With Purported Telemedicine Companies

I. Introduction

The Office of Inspector General (OIG) has conducted dozens of investigations of fraud schemes involving companies that purported to provide telehealth, telemedicine, or telemarketing services (collectively, Telemedicine Companies) and exploited the growing acceptance and use of telehealth. For example, in some of these fraud schemes Telemedicine Companies intentionally paid physicians and nonphysician practitioners (collectively, Practitioners) kickbacks to generate orders or prescriptions for medically unnecessary durable medical equipment, genetic testing, wound care items, or prescription medications, resulting in submissions of fraudulent claims to Medicare, Medicaid, and other Federal health care programs. These fraud schemes vary in design and operation, and they have involved a wide range of different individuals and types of entities, including international and domestic telemarketing call centers, staffing companies, Practitioners, marketers, brokers, and others.

One common element of these schemes is the way Telemedicine Companies have used kickbacks to aggressively recruit and reward Practitioners to further the fraud schemes. Generally, the Telemedicine Companies arrange with Practitioners to order or prescribe medically unnecessary items and services for individuals (referred to here as ''purported patients'') who are solicited and recruited by Telemedicine Companies. In many of these arrangements, Telemedicine Companies pay Practitioners in exchange for ordering or prescribing items or services: (1) for purported patients with whom the Practitioners have limited, if any, interaction; and (2) without regard to medical necessity. Such payments are sometimes described as payment per review, audit, consult, or assessment of medical charts. Telemedicine Companies often tell Practitioners that they do not need to contact the purported patient or that they only need speak to the purported patient by telephone. In addition, Practitioners are not given an opportunity to review the purported patient's real medical records. Furthermore, the Telemedicine Company may direct Practitioners to order or prescribe a preselected item or service, regardless of medical necessity or clinical appropriateness. In many cases, the Telemedicine Company sells the order or prescription generated by Practitioners to other individuals or entities that then fraudulently bill for the unnecessary items and services.

These schemes raise fraud concerns because of the potential for considerable harm to Federal health care programs and their beneficiaries, which may include: (1) an inappropriate increase in costs to Federal health care programs for medically unnecessary items and services and, in some instances, items and services a beneficiary never receives; (2) potential to harm beneficiaries by, for example, providing medically unnecessary care, items that could harm a patient, or improperly delaying needed care; and (3) corruption of medical decision-making.

OIG encourages Practitioners to exercise caution and use heightened scrutiny when entering into arrangements with Telemedicine Companies that have one or more of the suspect characteristics described below. This Special Fraud Alert provides information to help Practitioners identify potentially suspect arrangements with Telemedicine Companies.

II. Multiple Federal Laws Implicated

The schemes described above may implicate multiple Federal laws, including the Federal anti kickback statute. The Federal anti-kickback statute is a criminal law that prohibits knowingly and willfully soliciting or receiving (or offering or paying) any remuneration in return for (or to induce), among other things, referrals for, or orders of, items or services reimbursable by a Federal health care program. One purpose of the Federal anti-kickback statute is to protect patients from improper medical referrals or recommendations by health care professionals and others who may be influenced by financial incentives.

When a party knowingly and willfully pays remuneration to induce or reward referrals of items or services payable by a Federal health care program, the Federal anti-kickback statute is violated. By its terms, the statute ascribes liability to parties on both sides of an impermissible kickback transaction. Practitioner arrangements with Telemedicine Companies may also lead to criminal, civil, or administrative liability under other Federal laws including, for example, OIG's exclusion authority related to kickbacks, the Civil Monetary Penalties Law provision for kickbacks, the criminal health care fraud statute, and the False Claims Act. Practitioners may be personally liable for these types of arrangements, including for submitting or causing the submission of claims if they are involved in ordering or prescribing medically unnecessary items or services.

III. Recent Enforcement Experience

In recent years, OIG and the Department of Justice (DOJ) have investigated numerous criminal, civil, and administrative fraud cases involving kickbacks from Telemedicine Companies to Practitioners who inappropriately ordered or prescribed items or services reimbursable by Federal health care programs in exchange for remuneration. In those cases, Practitioners, Telemedicine Companies, and other participants in schemes have been held civilly, criminally, and administratively liable for: (1) paying or receiving a payment in violation of the Federal anti-kickback statute, (2) causing a submission of claims in violation of the False Claims Act, and/or (3) other Federal criminal laws.

While the facts and circumstances of each case differed, often they involved at least one Practitioner ordering or prescribing items or services for purported patients they never examined or meaningfully assessed to determine the medical necessity of items or services ordered or prescribed. In addition, Telemedicine Companies commonly paid Practitioners a fee that correlated with the volume of federally reimbursable items or services ordered or prescribed by the Practitioners, which was intended to and did incentivize a Practitioner to order medically unnecessary items or services. These types of volume-based fees not only implicate and potentially violate the Federal anti-kickback statute, but they also may corrupt medical decision-making, drive inappropriate utilization, and result in patient harm.

IV. Suspect Characteristics

Based on OIG's and DOJ's enforcement experience, we have developed the below list of suspect characteristics related to Practitioner arrangements with Telemedicine Companies which, taken together or separately, could suggest an arrangement that presents a heightened risk of fraud and abuse. This list is illustrative, not exhaustive, and the presence or absence of any one of these factors is not determinative of whether a particular arrangement with a Telemedicine Company would be grounds for legal sanctions.

- The purported patients for whom the Practitioner orders or prescribes items or services were identified or recruited by the Telemedicine Company, telemarketing company, sales agent, recruiter, call center, health fair, and/or through internet, television, or social media advertising for free or low out-of-pocket cost items or services.
- The Practitioner does not have sufficient contact with or information from the purported patient to meaningfully assess the medical necessity of the items or services ordered or prescribed.
- The Telemedicine Company compensates the Practitioner based on the volume of items or services ordered or prescribed, which may be characterized to the Practitioner as compensation based on the number of purported medical records that the Practitioner reviewed.
- The Telemedicine Company only furnishes items and services to Federal health care program beneficiaries and does not accept insurance from any other payor.
- The Telemedicine Company claims to only furnish items and services to individuals who are not Federal health care program beneficiaries but may in fact bill Federal health care programs.
- The Telemedicine Company only furnishes one product or a single class of products (*e.g.,* durable medical equipment, genetic testing, diabetic supplies, or various prescription creams), potentially restricting a Practitioner's treating options to a predetermined course of treatment.
- The Telemedicine Company does not expect Practitioners (or another Practitioner) to follow up with purported patients nor does it provide Practitioners with the information required to follow up with purported patients (*e.g.,* the Telemedicine Company does not require Practitioners to discuss genetic testing results with each purported patient).

Practitioners who enter into arrangements with Telemedicine Companies in which one or more of these suspect characteristics are present should exercise care and may face criminal, civil, or administrative liability depending on the facts and circumstances. This Special Fraud Alert is not intended to discourage legitimate telehealth arrangements. For example, OIG is aware that many Practitioners have appropriately used telehealth services during the current public health emergency to provide medically necessary care to their patients. However, OIG encourages Practitioners to use heightened scrutiny, exercise caution, and consider the above list of suspect criteria prior to entering into arrangements with Telemedicine Companies. This Special Fraud Alert does not alter any person's obligations under any applicable statutes or regulations, including those governing the billing or submission of Federal health care program claims.

For more information on telehealth-related issues, please visit our website, which includes additional materials relating to the provision of telehealth. If you have information about Practitioners, Telemedicine Companies, or other individuals or entities engaging in any of the activities described above, please contact the OIG Hotline at *https://oig.hhs.gov/fraud/report-fraud* or by phone at 1–800–447–8477 (1–800–HHS–TIPS).

Dated: August 17, 2022.

Gregory D. Demske,

Acting Principal Deputy Inspector General.

[FR Doc. 2022–18063 Filed 8–22–22; 8:45 am]

BILLING CODE 4150–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council, September 07, 2022, 10:00 a.m. to September 08, 2022, 2:00 p.m., National Institutes of Health, Building 31, 31 Center Drive, Bethesda, MD 20892 which was published in the **Federal Register** on December 29, 2021, 304543.

The meeting notice is amended to change and adjust the format of the meeting from Regular to Video Assisted Meeting. The meeting is partially closed to the public.