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.

Dated: August 18, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–18135 Filed 8–22–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting of the National Advisory Council for Biomedical imaging and Bioengineering.

The meeting will be open to the public as indicated below. Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting website (*http://videocast.nih.gov/*).

The meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Biomedical Imaging and Bioengineering.

Date: September 13, 2022.

Open: 12 p.m. to 3 p.m.

Agenda: Report from Institute Director, other Institute Staff and presentations of task group.

Place: National Institutes of Health, Democracy II, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Closed: 3 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Democracy II, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: David T. George, Ph.D., Associate Director for Research Administration, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Boulevard, Suite 200, Room 239, Bethesda, Maryland 20892, *georged@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *https://www.nibib.nih.gov/about-nibib/advisory-council,* where an agenda and any additional information for the meeting will be posted when available.

Dated: August 18, 2022.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–18160 Filed 8–22–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Mental Health Council.

The meeting will be held as a virtual meeting and is open to the public. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov/*).

A portion of this meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Mental Health Council.

Date: September 20–21, 2022.

Open: September 20, 2022, 12 p.m. to 4:30 p.m.

Agenda: Presentation of the NIMH Director's Report and discussion of NIMH programs.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Closed: September 21, 2022, 12 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Tracy L. Waldeck, Ph.D., Director, Division of Extramural Activities, National Institute of Mental Health, NIH, DHHS, Neuroscience Center, 6001 Executive Boulevard, Bethesda, MD 20892, (301) 480–6833, *tracy.waldeck@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *www.nimh.nih.gov/about/advisory-boards-and-groups/namhc/index.shtml,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: August 18, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–18145 Filed 8–22–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Complementary and Integrative Health Special Emphasis Panel; Early Phase Clinical Trials of Natural Products (NP).

Date: September 30, 2022.

Time: 10 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.