consolidation of the 0910–0012 collection into this collection in 2004, we have included the estimated recordkeeping burden for medicated feed adverse event reports as part of our estimate of the recordkeeping burden of all mandatory adverse event reports for new animal drugs. To improve the clarity of our estimates we have added a row to table 2, on which we separately report our recordkeeping estimate for medicated feed adverse event reports (20 hours).

The burden of this collection has changed. There was a slight increase in the estimated number of reports submitted to FDA under total annual responses (by 7.8 responses) and there was a slight overall decrease in burden hours (by 1.75 hours). This minor fluctuation in responses and hours is due to the normal variation in the submission of reports to FDA, the correction of mathematical errors, and a change in reporting methodology (addition of a new row to table 1 and table 2).

We continually strive to improve our systems for collecting and analyzing drug experience reports and adverse event reports. To that end, we have developed an electronic submission system by which Form FDA 2301 may be submitted to the Agency. For Form FDA 1932a, we have a fillable electronic form available online, which can be submitted by email to FDA Center for Veterinary Medicine. We specifically invite comment from respondents on the utility of these reporting forms. Electronic adverse event reporting for approved new animal drugs (including mandatory reporting under §514.80(b) and voluntary reporting) has been approved under OMB control number 0910–0645. Reporting and recordkeeping associated with the indexed drug experience reports and adverse event reports is required under OMB control number 0910–0612.


Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2018–02234 Filed 2–2–18; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meetings Announcement for the Physician-Focused Payment Model Technical Advisory Committee Required by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

ACTION: Notice of public meetings.

SUMMARY: This notice announces the 2018 meetings of the Physician-Focused Payment Model Technical Advisory Committee (hereafter referred to as “the Committee”) which will be held in Washington, DC. This meeting will include voting and deliberations on proposals for physician-focused payment models (PFPMs) submitted by members of the public. All meetings are open to the public.

DATES: The 2018 PTAC meetings will occur on the following dates:
• Monday–Tuesday, March 26–27, 2018, from 9:00 a.m. to 5:00 p.m. ET
• Thursday–Friday, June 14–15, 2018, from 9:00 a.m. to 5:00 p.m. ET
• Thursday–Friday, September 6–7, 2018, from 9:00 a.m. to 5:00 p.m. ET
• Monday–Tuesday, December 10–11, 2018, from 9:00 a.m. to 5:00 p.m. ET

Please note that times are subject to change. If the times change, registrants will be notified directly via email.

ADDRESSES: All PTAC meetings will be held in the Great Hall of the Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201.


SUPPLEMENTARY INFORMATION:
I. Purpose. The Physician-Focused Payment Model Technical Advisory Committee (“the Committee”) is required by the Medicare Access and CHIP Reauthorization Act of 2015, 42 U.S.C. 1395ee. This Committee is also governed by provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees. In accordance with its statutory mandate, the Committee is to review physician-focused payment model proposals and prepare recommendations regarding whether such models meet criteria that were established through rulemaking by the Secretary of Health and Human Services (the Secretary). The Committee is composed of 11 members appointed by the Comptroller General.

II. Agenda. At each scheduled meeting, the Committee will hear presentations on PFPMs that are ready for Committee deliberation. The presentations will be followed by public comment and Committee deliberation. If the Committee completes deliberations, voting will occur on recommendations to the Secretary of Health and Human Services. There will be time allocated for public comment on agenda items. Documents will be posted on the Committee website and distributed on the Committee listserv prior to the public meeting. The agenda is subject to change. If the agenda does change, we will inform registrants and update the website.

III. Meeting Attendance. These meetings are open to the public. The public may also attend via conference call or view the meeting via livestream at www.hhs.gov/live. The conference call dial-in information will be sent to registrants prior to the meeting.

Meeting Registration: The public may attend the meetings in-person, participate by phone via audio teleconference, or view the meeting via livestream. Space is limited and registration is preferred in order to attend in-person or by phone. Registration may be completed online at www.regonline.com/PTACMeetings.

The following information is submitted when registering:
Name: Company/organization name:
Postal address:
Email address:
A confirmation email will be sent to registrants shortly after completing the registration process.

IV. Special Accommodations. If sign language interpretation or other reasonable accommodation for a disability is needed, please contact Angela Tejeda, no later than one week prior to the scheduled meeting. Please submit your requests by email to Angela.Tejeda@hhs.gov or by calling 202–401–8297.


Additional material for this meeting can be found on the ASPE PTAC website. For updates and announcements, please use the link to subscribe to the ASPE PTAC email listserv.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

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

The meetings 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.


Date: February 21–22, 2018.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Barbara A. Woynarowska, Ph.D., Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7007, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 402–7172, woynarowskab@extra.niddk.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)


David Clary,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–02253 Filed 2–2–18; 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 Closed Meetings

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

The meetings 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 Institute of Mental Health Special Emphasis Panel; Clinical Trial and K Awards Review Meeting.

Date: February 27, 2018.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: David I. Sommers, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Room 6154, MSC 9606, Bethesda, MD 20892, 301–443–7861, dsommers@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)


Melanie J. Pantoja,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–02251 Filed 2–2–18; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, March 13, 2018, 4:00 p.m. to March 14, 2018, 5:00 p.m., Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, North Bethesda, MD 20852 which was published in the Federal Register on January 11, 2018, 83 FR 1378.

This meeting notice is amended to change the meeting name from “TEP–1: Development of Software Tools for Post Radiation Therapy Surveillance” to