contact information to 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 this 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.gpo.gov/fdsys/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.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002 or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Michail Alterman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4245, Silver Spring, MD 20993, 240–402–9355; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''CMC Postapproval Manufacturing Changes for Specified Biological Products To Be Documented in Annual Reports.'' Applicants must notify the Agency of a change to an approved BLA in accordance with all statutory and regulatory requirements—including section 506A of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 356a) and 21 CFR 601.12. Section 506A of the FD&C Act provides requirements for making and reporting manufacturing changes to an approved application or license and for distributing a drug product made with such changes. Under § 601.12, each post-approval change in the product, production process, quality controls, equipment, facilities, or responsible personnel established in an approved BLA is categorized into one of three reporting categories:

- *Major change:* Applicants must submit and receive FDA's approval of a supplement to the BLA before the product produced with the manufacturing change is distributed.
- *Moderate change:* Applicants must submit a supplement at least 30 days before the product is distributed or, in some cases, the product may be distributed immediately upon FDA's receipt of the supplement.
- *Minor change:* Applicants may proceed with the change but must notify FDA of the change in an annual report.

This draft guidance provides recommendations for changes that generally should be documented in an annual report. It discusses the contents of an annual report notification and lists examples of postapproval manufacturing changes for BLAs that FDA generally considers to have a minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as they may relate to the safety or effectiveness of the product and, therefore, generally should be documented in an annual report.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on CMC postapproval manufacturing changes for specified biological products to be documented in annual reports. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in § 601.12 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *https://www.regulations.gov.*

Dated: August 3, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–16718 Filed 8–8–17; 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 next meeting 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 PTAC meeting will occur on the following dates:

- Thursday—Friday, September 7–8, 2017, 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: The September 7–8, 2017 meeting will be held at the Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC, 20201.

FOR FURTHER INFORMATION CONTACT: Ann Page, Designated Federal Official, at the Office of Health Policy, Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, 200 Independence Ave. SW., Washington, DC 20201, (202) 690–6870.

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 the September 7–8, 2017, 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 Web site 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 our Web site to reflect any changes.

III. Meeting Attendance

The meeting is 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 or participate by phone via audio teleconference. 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 Registration.*

The following information is submitted when registering:

Name:
Company/organization name:
Postal address:
Email address:

Persons wishing to attend this meeting must register by following the instructions in the ''Meeting Registration'' section of this notice. 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 August 24, 2017. Please submit your requests by email to *Angela.Tejeda@hhs.gov* or by calling 202–401–8297.

V. Copies of the PTAC Charter and Meeting Material

The Secretary's Charter for the Physician-Focused Payment Model Technical Advisory Committee is available on the ASPE Web site at *https://aspe.hhs.gov/charter-physician-focused-payment-model-technical-advisory-committee.*

Additional material for this meeting can be found on the PTAC Web site. For updates and announcements, please use the link to subscribe to the PTAC email listserv.

Dated: August 3, 2017.

John R. Graham,

Acting Assistant Secretary for Planning and Evaluation.

[FR Doc. 2017–16784 Filed 8–8–17; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Informatics Support for NIDA (8940).

Date: August 31, 2017.

Time: 9:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: Hilton Garden Inn Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Lyle Furr, Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 4227, MSC 9550, 6001 Executive Boulevard, Bethesda, MD 20892–9550, (301) 827–5702, *lf33c.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: August 3, 2017.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–16733 Filed 8–8–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel, RFA–MH–17–650: Implementation Science for the Prevention and Treatment of Mental and/or Substance Use Disorders in Low- and Middle-income Countries (U01).

Date: September 4–5, 2017.

Time: 8:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: President Hotel, 4 Alexander Road, Bantry Bay, Cape Town, 8001, South Africa.

Contact Person: Seetha Bhagavan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892, (301) 237–9838, *bhagavas@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, PAR–17–076: High-End Instrumentation (HEI) Grant Program (S10).

Date: September 12, 2017.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel at Pentagon City, 1250 South Hayes Street, Arlington, VA 22202.

Contact Person: Songtao Liu, MD, Scientific Review Officer, Center for