Therefore, you should always check the Agency’s Web site 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 committee will discuss appropriate patient selection criteria and clinical trial design features, including acceptable endpoints, for demonstrating clinical benefit for drugs intended to treat interstitial cystitis and bladder pain syndrome. The committee will also discuss whether bladder pain syndrome and interstitial cystitis reflect overlapping or different populations, and whether it is appropriate to assess efficacy in the same way for both conditions.

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 Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA’s Web site after the meeting. Background material is available at https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm. Scroll down to the appropriate advisory committee meeting link.

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 November 22, 2017, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. 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 November 14, 2017. 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 November 15, 2017.

Persons attending FDA’s advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

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 special accommodations due to a disability, please contact Kalyani Bhatt at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site 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).


Anna K. Abram,
Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–18131 Filed 8–25–17; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the National Advisory Committee on Rural Health and Human Services

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of Meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, notice is hereby given of a National Advisory Committee on Rural Health and Human Services (NACRHHS) meeting. The meeting will be open to the public. Information about the NACRHHS meeting can be obtained by accessing the following Web site: http://www.hrsa.gov/advisorycommittees/rural/.

DATES: The meeting will be held on September 11, 2017, 8:45 a.m. to 5:00 p.m. MDT; September 12, 2017, 8:30 a.m. to 5:15 p.m. MDT; and September 13, 2017, 8:30 a.m. to 11:00 a.m. MDT.

ADDRESSES: This meeting will be held at the Spring Hill Suites located at 424 E. Parkcenter Blvd., Boise, Idaho 83706, (208) 342–1044.

FOR FURTHER INFORMATION CONTACT:
Steve Hirsch, MSLS, Administrative Coordinator, National Advisory Committee on Rural Health and Human Services, Health Resources and Services Administration, Parklawn Building, 17W29C, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443–0835, Fax (301) 443–2803.

SUPPLEMENTARY INFORMATION:

NACRHHS provides counsel and recommendations to the Secretary with respect to the delivery, research, development, and administration of health and human services in rural areas.

The meeting on Monday, September 11, will be called to order at 8:45 a.m. by the Chairperson of the Committee, The Honorable Ronnie Musgrove. The Committee will examine the issue of suicide in rural areas and the issue of Rural Health Clinic Modernization. The day will conclude with a period of public comment at approximately 5:15 p.m.

The Committee will break into subcommittees and depart for site visits Tuesday morning, September 12, at approximately 8:15 a.m. Subcommittees will visit First Baptist Church, 126 S. Hayes Avenue in Emmett, Idaho and the North Canyon Medical Center, 267 N. Canyon Drive in Gooding, Idaho. The day will conclude at the Spring Hill Suites with a period of public comment at approximately 5:00 p.m.

The Committee will meet to summarize key findings and develop a work plan for the next quarter and the following meeting on Wednesday morning, September 13, at 8:30 a.m. Persons interested in attending any portion of the meeting should contact Alfred Delena at the Federal Office of Rural Health Policy (FORHP) via telephone at (301) 443–3388 or by email at ADelena@hrsa.gov. The Committee meeting agenda will be posted on the Committee’s Web site at http://www.hrsa.gov/advisorycommittees/rural/.

Amy McNulty,
Acting McNulty, Division of the Executive Secretariat.

[FR Doc. 2017–18139 Filed 8–25–17; 8:45 am]
BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice of Intent To Establish the Pain Management Best Practices Inter-Agency Task Force and Request for Nominations for Task Force Members

AGENCY: Office of the Assistant Secretary for Health, Office of the
Secretary, U.S. Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The U.S. Department of Health and Human Services (HHS) hereby gives notice of its intent to establish the Pain Management Best Practices Inter-Agency Task Force (Task Force) pursuant to section 101 of the Comprehensive Addiction and Recovery Act of 2016. The Task Force will consist of representatives of specific Federal agencies and non-federal individuals and entities who represent diverse disciplines and views. The Task Force will provide advice and recommendations for development of best practices for pain management and prescribing pain medication and a strategy for disseminating such best practices to relevant Federal agencies and the general public.

Through this notice, HHS is also requesting nominations of individuals who are interested in being considered for appointment to the Task Force. Resumes or curricula vitae from qualified individuals who wish to be considered for appointment as a member of the Task Force are currently being accepted.

DATES: Nominations must be received no later than close of business September 27, 2017.

ADDRESSES: All nominations must be submitted via email to the attention of Vanila M. Singh, M.D., Chief Medical Officer at PainTaskforce@hhs.gov.

FOR FURTHER INFORMATION CONTACT: Vanila M. Singh, M.D., Chief Medical Officer, Office of the Assistant Secretary for Health; U.S. Department of Health and Human Services; Telephone: (202) 205–3041; Fax: (202) 205–2107; Email address: PainTaskforce@hhs.gov. When the charter for the Task Force has been filed with the appropriate Congressional committees and the Library of Congress, this document will be made available online. Web site information about activities of the Task Force will be provided when the URL has been identified. The charter will include detailed information about the purpose, function, and structure of the Task Force.

SUPPLEMENTARY INFORMATION: Section 101 of the Comprehensive Addiction and Recovery Act of 2016 (Pub. L. 114–198) (CARA) authorizes the Secretary of HHS, in cooperation with the Secretary of Veterans Affairs and the Secretary of Defense, to convene the Task Force. The Task Force will consist of representatives of specific Federal agencies and non-federal individuals and entities who represent diverse disciplines and views. The Task Force will identify, review, and determine whether there are gaps or inconsistencies in best practices among Federal agencies; propose updates to best practices and recommendations on addressing gaps or inconsistencies; provide the public with an opportunity to comment on any proposed updates and recommendations; and develop a strategy for disseminating information about best practices.

The Task Force will provide advice and recommendations for development of best practices for pain management and prescribing pain medication and a strategy for disseminating such best practices to relevant Federal agencies and the general public. The functions of the Task Force will be solely advisory in nature. The Task Force will be established as a non-discretionary Federal advisory committee.

When the charter for the Task Force is approved, it will be filed with the appropriate Congressional committees and the Library; hard copies of this document will be made available upon request. The approved charter will also be accessible online.

Objectives and Scope of Activities. The Secretary of HHS, in cooperation with the Secretary of Veterans Affairs and the Secretary of Defense, shall convene the Task Force to identify, review, and determine whether there are gaps or inconsistencies in best practices among Federal agencies; propose updates to best practices and recommendations on addressing gaps or inconsistencies; provide the public with an opportunity to comment on any proposed updates and recommendations; and develop a strategy for disseminating information about best practices.

Membership and Designation. The Task Force shall consist of not more than 30 members. The Assistant Secretary for Health of HHS shall select the Chair. The Chair may select a Vice-Chair from among Task Force members. The members of the Task Force shall include currently licensed and practicing physicians, dentists, and non-physician prescribers; currently licensed and practicing pharmacists and pharmacies; experts in the fields of pain research and addiction research, including adolescent and young adult addiction; experts on the health of, and prescription opioid use disorders in, members of the Armed Forces and veterans; and experts in the field of minority health. The members of the Task Force shall also include individuals who are appointed to serve under CARA subsection 101(c)(5) as representatives of pain management professional organizations; the mental health treatment community; the addiction treatment community, including individuals in recovery from substance use disorder; pain advocacy groups, including patients; veteran service organizations; groups with expertise on overdose reversal, including first responders; State medical boards; and hospitals. The Secretary shall ensure that the membership of the Task Force includes individuals who represent rural and underserved areas. The composition of the Task Force shall also include federal members who shall serve as representatives for the following departments and agency: The Department of Health and Human Services and relevant HHS agencies, the Department of Veterans Affairs, the Department of Defense, and the Office of National Drug Control Policy.

Members who are not officers or employees of the United States Government and who are not appointed as special government employees (SGEs). Members of the Task Force who are officers or employees of the United States Government shall be appointed to serve at the discretion of the head of the respective Federal departments and agency. Members appointed as SGEs shall receive per diem and reimbursement for travel expenses incurred in relation to performing duties for the Task Force, as authorized by law under 5 U.S.C. 5703 for persons who are employed intermittently to perform services for the Federal government in accordance with Federal travel regulations. Members appointed as representatives of a designated entity under CARA subsection 101(c)(5) may be allowed to receive per diem and reimbursement for any applicable expenses that are incurred to conduct business related to the Task Force.

Estimated Number and Frequency of Meetings. The Task Force shall meet not less than two times a calendar year,
depending upon the availability of funds. The meetings may be conducted by teleconference or videoconference at the discretion of the Designated Federal Officer. The meetings shall be open to the public, except as determined otherwise by the Secretary, or other official to whom authority has been delegated, in accordance with the guidelines under Government in the Sunshine Act, 5 U.S.C. 552b(c). Notice of all meetings shall be provided to the public in accordance with the Federal Advisory Committee Act. Meetings shall be conducted and records of the proceedings shall be kept, as required by applicable laws and departmental policies. A quorum is required for the Task Force to meet to conduct business. A quorum shall consist of a majority of the Task Force’s members. When the Secretary or the Secretary’s designee determines that a meeting shall be closed or partially closed to the public, in accordance with provisions of Government in the Sunshine Act, 5 U.S.C. 552b(c), then a report shall be prepared by the Designated Federal Officer that includes, at a minimum, a list of members and their business addresses, the Task Force’s functions, date and place of the meeting, and a summary of the Task Force’s activities and recommendations made during the fiscal year. A copy of the report shall be provided to the Department Committee Management Officer.

Nominations: Nominations, including self-nominations, of individuals who have the specified expertise and knowledge will be considered for appointment as members of the Task Force. A nomination should include, at a minimum, the following for each nominee: (1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination, and a statement from the nominee that indicates that the individual is willing to serve as a member of the Task Force, if selected; (2) the nominator’s name, address, and daytime telephone number, and the address, telephone number, and email address of the individual being nominated; and (3) a current copy of the nominee’s curriculum vitae or resume, which should be limited to no more than 10 pages.

Every effort will be made to ensure that the composition of the Task Force includes individuals from various geographic locations, including rural and underserved areas; racial and ethnic minorities; genders, and persons living with disabilities; individuals other than officers or employees of the United States government being considered for appointment as members of the Task Force will be required to complete and submit a report of their financial holdings. An ethics review must be conducted to ensure that individuals appointed as members of the Task Force are not involved in any activity that may pose a potential conflict of interest for the official duties that are to be performed. This is a federal ethics requirement that must be satisfied upon entering the position and annually throughout the established term of appointment on the Task Force.


Donald Wright,
Acting Assistant Secretary for Health.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before September 27, 2017.

ADDRESSES: Submit your comments to OIRA_submission@omb.eop.gov or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, Sherrette.Funn@hhs.gov or (202) 795–7714. When submitting comments or requesting information, please include the document identifier 0990-New-30D and project title for reference

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Project Title: Assessment of the Impact of Energy Development on the Behavioral Health of Women in Western North Dakota and Eastern Montana. The Region VIII Office of the Assistant Secretary for Health (OASH), Office on Women’s Health (OWH).

Abstract: The Office on Women’s Health (OWH) in the Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services (HHS) is requesting approval from the Office of Management and Budget (OMB) for a new data collection for the Assessment of the Impact of Energy Development on the Behavioral Health of Women in Western North Dakota and Eastern Montana. Its mission is to provide national leadership and coordination to improve the health of women and girls through policy, education and model programs. Region VIII OASH/OWH is interested in improving women’s behavioral health associated with the impact of energy development through gender based data collection and analysis. The discovery and subsequent development of the Parshall Oil Field within the Bakken region of Western North Dakota has led to significant economic opportunity and population growth in the region (Eastern Montana and Western North Dakota). Rapid population growth has many intended and unintended consequences, both positive and negative, on the social and economic environment of the region and, consequently, the population’s health and well-being.

Need and Proposed Use of the Information: There are well-documented environmental health issues associated with oil and gas development, including air, water, soil, noise, and light pollution. However, there are additional social, physical and mental health effects that are less well documented. Current research is very limited, but preliminary evidence suggests that women have unmet behavioral health needs due in part to the energy development and population surge in region. These data will ultimately be used to understand the impact of energy development on the behavioral health of women in Eastern Montana and Western North Dakota.