

consistent with published research on this subject which supports a priority review multiplier in the range of 1.48 to 2.35 (Ref. 1). Using FY 2015 figures, the costs of a priority and standard review are estimated using the following formula:

$$(25 \alpha \times 1.67) + (31 \alpha) = \$289,352,000$$

Where “α” is the cost of a standard review and “α times 1.67” is the cost of a priority review. Using this formula, the cost of a standard review for NME NDAs and BLAs is calculated to be \$3,977,000 (rounded to the nearest thousand dollars) and the cost of a priority review for NME NDAs and BLAs is 1.67 times that amount, or \$6,642,000 (rounded to the nearest thousand dollars). The difference between these two cost estimates, or \$2,665,000, represents the incremental cost of conducting a priority review rather than a standard review.

For the FY 2017 fee, FDA will need to adjust the FY 2015 incremental cost by the average amount by which FDA’s average costs increased in the 3 years prior to FY 2016, to adjust the FY 2015 amount for cost increases in FY 2016. That adjustment, published in the **Federal Register** on July 28, 2016 (see 81 FR 49674 at 49676), setting the FY 2017 PDUFA fee, is 1.5468 percent for the most recent year, not compounded. Increasing the FY 2015 incremental priority review cost of \$2,665,000 by 1.5468 percent results in an estimated cost of \$2,706,000 (rounded to the nearest thousand dollars). This is the rare pediatric disease priority review user fee amount for FY 2017 that must be submitted with a priority review voucher for a human drug application in FY 2017, in addition to any PDUFA fee that is required for such an application.

III. Fee Schedule for FY 2017

The fee rate for FY 2017 is set out in table 1:

TABLE 1—RARE PEDIATRIC DISEASE PRIORITY REVIEW SCHEDULE FOR FY 2017

Fee category	Fee rate for FY 2017
Application submitted with a rare pediatric disease priority review voucher in addition to the normal PDUFA fee	\$2,706,000

IV. Implementation of Rare Pediatric Disease Priority Review User Fee

Under section 529(c)(4)(A) of the FD&C Act, the priority review user fee is due (i.e. the obligation to pay the fee is incurred) when a sponsor notifies

FDA of its intent to use the voucher. Section 529(c)(4)(B) of the FD&C Act specifies that the application will be considered incomplete if the priority review user fee and all other applicable user fees are not paid in accordance with FDA payment procedures. In addition, section 529(c)(4)(C) specifies that FDA may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section of the FD&C Act. Beginning with FDA’s appropriation for FY 2015, the annual appropriation language states specifically that “priority review user fees authorized by 21 U.S.C. 360n and 360ff (section 529 of the FD&C Act) shall be credited to this account, to remain available until expended.” (Pub. L. 113–235, Section 5, Division A, Title VI).

The rare pediatric disease priority review fee established in the new fee schedule must be paid for any application that is received on or after October 1, 2016. In order to comply with this requirement, the sponsor must notify FDA 90 days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the date on which the sponsor intends to submit the application.

Upon receipt of this notification, FDA will issue an invoice to the sponsor who has incurred a rare pediatric disease priority review voucher fee. The invoice will include instructions on how to pay the fee via wire transfer or check.

As noted in section II, if a sponsor uses a rare pediatric disease priority review voucher for a human drug application, the sponsor would incur the rare pediatric disease priority review voucher fee in addition to any PDUFA fee that is required for the application. The sponsor would need to follow FDA’s normal procedures for timely payment of the PDUFA fee for the human drug application.

V. Reference

The following reference is on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Ridley, D.B., H.G. Grabowski, and J.L. Moe, “Developing Drugs for Developing Countries,” *Health Affairs*, vol. 25, no. 2, pp. 313–324, 2006.

Dated: September 26, 2016.
Leslie Kux,
Associate Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

State Health Departments Coordinating Center of the Jurisdictional Approach To Curing Hepatitis C Among HIV/HCV Coinfected People of Color Demonstration Project Supported by the Secretary’s Minority AIDS Initiative Fund

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

ACTION: Notice of a deviation from competition requirements to make a single-source award related to the Jurisdictional Approach to Curing Hepatitis C (HCV) among HIV/HCV Coinfected People of Color demonstration project.

SUMMARY: HRSA’s HIV/AIDS Bureau (HAB) awarded a non-competitive single source cooperative agreement to National Alliance of State and Territorial AIDS Directors (NASTAD) for approximately \$977,400 in the Secretary’s Minority AIDS Initiative Funds (SMAIF) as authorized under the Consolidated Appropriations Act, 2016 (Pub L. 114–113), Division H, Title II. Subject to the availability of funds and NASTAD’s satisfactory performance, HAB will also issue non-competitive, single-source awards of approximately \$750,000 each in fiscal years (FY) 2017 and 2018. This will allow NASTAD to facilitate the participation of up to two Ryan White HIV/AIDS Program Part B recipients in the Jurisdictional Approach to Curing Hepatitis C among HIV/HCV Coinfected People of Color demonstration project over its 3-year project period.

FOR FURTHER INFORMATION CONTACT: Harold J. Phillips, Director, Office of Training and Capacity Development, HAB/HRSA, 5600 Fishers Lane, Room 9N–114, Rockville, MD 20857, by email at hphillips@hrsa.gov or by phone at (301) 443–8109.

SUPPLEMENTARY INFORMATION:
Recipient of the Award: National Alliance of State and Territorial AIDS Directors.
Period of Supplemental Funding: September 30, 2016–September 29, 2019.

Funding Amount: Up to \$977,400 in FY 2016, and subject to availability of appropriated funds, approximately \$750,000 in FYs 2017 and 2018.

Authority: Consolidated Appropriations Act, 2016 (Pub L. 114–113), Division H, Title II CFDA Number: 93.928.

Justification: The Jurisdictional Approach to Curing Hepatitis C among HIV/HCV Coinfected People of Color demonstration project seeks to: (1) Increase jurisdiction-level capacity to provide comprehensive screening, care and treatment for HCV among HIV/HCV co-infected people particularly in disproportionately affected racial and ethnic minority communities; (2) increase the numbers of HIV/HCV co-infected people who are diagnosed with hepatitis C, treated, and cured; (3) identify and provide technical assistance for jurisdictions to reach goals (1) and (2); and, (4) develop a plan for evaluation of the program impact.

During the original application period, as outlined in Funding Opportunity Announcement HRSA–16–189, no Ryan White Part B recipients (States) applied. This non-competitive single source cooperative agreement award will provide important resources in a part of the country that would not otherwise have any coverage.

NASTAD is a national non-profit alliance of state health department program directors who are responsible for administering HIV/AIDS and viral hepatitis health care, prevention, education, and supportive services programs funded by state and federal governments. These include programs funded by the Centers for Disease Control and Prevention and HRSA. In working closely with its members, NASTAD is dedicated to reducing the incidence of HIV/AIDS and HCV infections in the U.S. and its territories, and supports the provision of comprehensive, compassionate, and high quality care and prevention services to all persons living with HIV/AIDS and HCV, by ensuring responsible and sound public policies and practices.

NASTAD's hepatitis team provides guidance and technical assistance to strengthen the capacity of state and local health departments to develop, maintain, and enhance comprehensive hepatitis programs that address the continuum from prevention through cure. This infrastructure, experience, and strategic partnership between state hepatitis coordinators and AIDS directors make NASTAD the appropriate entity to receive a single-source funding award in an effort to

facilitate engagement between the states and HRSA's viral hepatitis efforts.

Dated: September 26, 2016.

James Macrae,

Acting Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: 0990–New—60D]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, announces plans to submit a new Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, OS seeks comments from the public regarding the burden estimate below or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before November 29, 2016.

ADDRESSES: Submit your comments to *Information.Collection.Clearance@hhs.gov* or by calling (202) 690–5683.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier 0990–New—60D for reference.

Information Collection Request Title: Assessment of the Impact of Energy Development on the Behavioral Health of Women in Western North Dakota and Eastern Montana.

Abstract: Region VIII Office of the Assistant Secretary for Health (OASH), Office on Women's Health (OWH) is requesting approval from the Office of Management and Budget (OMB). 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) was established in 1991. Its mission is to provide national leadership and coordination to improve the health of women and girls through policy, education and model programs. The vision of the Office on Women's Health is that all women and

girls achieve the best possible health. OASH/OWH has ten regional offices located throughout the country. As a leader in women health, OWH supports the development of culturally-based, gender-sensitive programs to address health disparities. 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. 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. In 2013, The U.S. Department of Health and Human Services (HHS), Region VIII Offices, including the Office of the Assistant Secretary for Health (OASH), Office on Women's Health (OWH) began to have discussions directly with state/local contacts about the impact this was having on public health and the specific impacts on women. Given this history and context, the Region VIII OASH/OWH, is undertaking an assessment to examine the impact of energy development on women's behavioral health in Western North Dakota and Eastern Montana.

Likely Respondents: Data for this assessment will be collected through three mechanisms—a survey of women living in the assessment geography, approximately 20 focus groups with a cross-section of women and other key groups living in the assessment geography, and approximately 40 interviews with key leaders and stakeholders across a variety of governmental and non-governmental sectors. Combined, these data collection mechanisms will provide a quantitative and qualitative portrait of women's behavioral health in the region.