

21 CFR part	Topic	OMB Control No.
807, subpart E .....	Premarket Notification .....	0910-0120
812 .....	Investigational Device Exemption .....	0910-0078
801 .....	Medical Device Labeling Regulations .....	0910-0485
820 .....	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation .....	0910-0073
50, 56 .....	Protection of Human Subjects: Informed Consent; Institutional Review Boards .....	0910-0755
56 .....	Institutional Review Boards .....	0910-0130

Dated: July 22, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019-15889 Filed 7-25-19; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Rural Communities Opioid Response Program Performance Measures, OMB No. 0906-xxxx, New.

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

**ACTION:** Notice.

**SUMMARY:** In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

**DATES:** Comments on this ICR should be received no later than August 26, 2019.

**ADDRESSES:** Submit your comments, including the ICR title, to the desk officer for HRSA, either by email to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to (202) 395-5806.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443-1984.

#### SUPPLEMENTARY INFORMATION:

*Information Collection Request Title:* Rural Communities Opioid Response Program Performance Measures, OMB No. 0906-xxxx, New

*Abstract:* The Rural Communities Opioid Response Program (RCORP) is a multi-initiative program that aims to: (1) Support treatment for, and prevention of, substance use disorder (SUD), including opioid use disorder (OUD); and (2) reduce morbidity and mortality associated with SUD, to include OUD, by improving access to prevention, treatment, and recovery support services to high-risk rural communities. To support this purpose, RCORP grant initiatives include:

- RCORP-Planning grants to strengthen the capacity of multi-sector consortia to collaborate and develop plans to deliver SUD/OUD prevention, treatment, and recovery services in high-risk rural communities;
- RCORP-Implementation grants to fund established networks and consortia to deliver SUD/OUD prevention, treatment, and recovery activities in high-risk rural communities; and
- RCORP-Medication Assisted Treatment Expansion grants to enhance access to medication-assisted treatment within eligible hospitals, health clinics, or tribal organizations in high-risk rural communities.

Additionally, all RCORP grant award recipients will be supported by five cooperative agreements: RCORP-Technical Assistance, which provides extensive technical assistance to award recipients; RCORP-Evaluation, which will evaluate the impact of the RCORP initiative on rural communities; and three RCORP-Rural Centers of Excellence in Substance Use Disorders, which will disseminate best practices related to the treatment for, and prevention of, SUD within rural communities. A 60-day notice was published in the **Federal Register** on

April 12, 2019, vol. 84, No. 71; pp. 14949-14950. There were no public comments.

*Need and Proposed Use of the Information:* For this program, performance measures were developed to provide data on each RCORP initiative and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act of 1993. These measures cover the principal topic areas of interest to the Federal Office of Rural Health Policy (FORHP), including: (a) Provision of, and referral to, SUD treatment and support services; (b) SUD prevention, treatment, and recovery process and outcomes; (c) education of health care providers and community members; (d) number of fatal and non-fatal opioid-related overdoses; and (e) consortium strength and sustainability. All measures will speak to FORHP's progress toward meeting the goals set.

*Likely Respondents:* The respondents will be the grant award recipients of RCORP initiatives.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

## TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent (annually)	Total responses	Average burden per response (in hours)	Total burden hours
Rural Communities Opioid Response Program Performance Measures .....	243	2	486	5.66	2,750
Total .....	243	.....	486	.....	2,750

**Maria G. Button,**

*Director, Division of the Executive Secretariat.*

[FR Doc. 2019–15883 Filed 7–25–19; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### National Advisory Council on Nurse Education and Practice; Meeting Cancellation

**AGENCY:** Health Resources and Services Administration; Department of Health and Human Services.

**ACTION:** Notice of meeting cancellation.

**SUMMARY:** This is to notify the public that the previously scheduled September 24, 2019, meeting of the National Advisory Council on Nurse Education and Practice (NACNEP) is cancelled. This meeting was announced in the **Federal Register**, Vol. 84, No. 45 on Thursday, March 7, 2019 (FR Doc. 2019–04074 Filed 3–6–19). Future meetings will occur in calendar year 2020 and be announced through the **Federal Register** at a later date.

**FOR FURTHER INFORMATION CONTACT:** Tracy L. Gray, MBA, MS, RN, Chief, Advanced Nursing Education Branch, Designated Federal Officer, NACNEP, 5600 Fishers Lane, Rockville, Maryland 20857, telephone: (301) 945–3113 or email: [BHWNACNEP@hrsa.gov](mailto:BHWNACNEP@hrsa.gov).

**Maria G. Button,**

*Director, Division of the Executive Secretariat.*

[FR Doc. 2019–15894 Filed 7–25–19; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Health Resources and Service Administration Uniform Data System, OMB No. 0915–0193—Revision

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

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR must be received no later than September 24, 2019.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call Lisa Wright-Solomon, HRSA Information Collection Clearance Officer at (301) 443–1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the ICR title for reference.

*Information Collection Request Title:* Health Resources and Services Administration Uniform Data System, OMB No. 0915–0193—Revision.

*Abstract:* The Health Center Program, administered by HRSA, is authorized

under section 330 of the Public Health Service (PHS) Act, most recently amended by section 50901(b) of the Bipartisan Budget Act of 2018, Public Law 115–123. Health centers are community-based and patient-directed organizations that deliver affordable, accessible, quality, and cost-effective primary health care services to patients regardless of their ability to pay. Nearly 1,400 health centers operate approximately 12,000 service delivery sites that provide primary health care to more than 27 million people in every U.S. state, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin. HRSA uses the Uniform Data System (UDS) for annual reporting by certain HRSA award recipients, including Health Center Program awardees (those funded under section 330 of the PHS Act), Health Center Program look-alikes, and Nurse Education, Practice, Quality and Retention (NEPQR) Program awardees (specifically those funded under the practice priority areas of section 831(b) of the PHS Act).

*Need and Proposed Use of the Information:* HRSA collects UDS data annually to ensure compliance with legislative and regulatory requirements, improve clinical and operational performance, and report overall program accomplishments. These data help to identify trends over time, enabling HRSA to establish or expand targeted programs and to identify effective services and interventions that will improve the health of medically underserved communities. HRSA analyzes UDS data with other national health-related data sets to compare the Health Center Program patient populations and the overall U.S. population.

HRSA plans to continue aligning several clinical measures reported in the UDS with the Centers for Medicare & Medicaid Services' (CMS) electronic specified clinical quality measures (eCQM) and is considering the following changes for 2020 UDS data collection:

- *Retiring CMS126 Use of Appropriate Medications for Asthma:* The CMS eCQM is no longer being