**INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Adebayo Laniyonu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5400, Silver Spring, MD 20993–0002, 301–796–1392.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a guidance for industry entitled ''Microdose Radiopharmaceutical Diagnostic Drugs: Nonclinical Study Recommendations.'' This guidance is intended to assist sponsors of microdose radiopharmaceutical diagnostic drugs on the nonclinical studies recommended to support human clinical trials and marketing applications. This guidance incorporates comments received and finalizes the draft guidance of the same name issued on September 13, 2017 (82 FR 43025). The guidance includes a few editorial changes and a new sentence clarifying the definition of the term diagnostic radiopharmaceutical.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on nonclinical study recommendations for microdose radiopharmaceutical diagnostic drugs. 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. This guidance is not subject to Executive Order 12866.

## II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that 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 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively. The collection of information for radioactive drug research committees in 21 CFR 361.1 has been approved under OMB control number 0910–0053. The collection of information for the regulations on in vivo radiopharmaceuticals used for diagnosis and monitoring in 21 CFR 315.4, 315.5, and 315.6 has been approved under OMB control number 0910–0409.

## III. Electronic Access

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

Dated: August 15, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–17961 Filed 8–20–18; 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; The Maternal, Infant, and Early Childhood Home Visiting Program Statewide Needs Assessment Update

**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 a Supplemental Information Request (SIR) to the Office of Management and Budget (OMB) for review and approval. A 60-day Federal Register Notice was published in the **Federal Register** on April 24, 2018. There were seven public comments. Comments submitted during the first public review of this SIR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

**DATES:** Comments on this SIR should be received no later than September 20, 2018.

**ADDRESSES:** Submit your comments, including the Information Collection Request (ICR) Title, to the desk officer for HRSA, either by email to *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* or call (301) 443–1984.

**SUPPLEMENTARY INFORMATION:**

*Information Collection Request Title:* The Maternal, Infant, and Early Childhood Home Visiting Program Statewide Needs Assessment Update, OMB No. 0906–XXX, New.

*Abstract:* HRSA is requesting approval to collect updated statewide needs assessments from Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program awardees. The previous statewide needs assessment that was approved under OMB control number 0915–0333 has been discontinued. Eligible entities that are states, the District of Columbia, and non-profit organizations will submit statewide needs assessment updates in response to a forthcoming SIR. The MIECHV Program, authorized by section 511 of the Social Security Act, 42 U.S.C. 711, and administered by HRSA in partnership with the Administration for Children and Families, supports voluntary, evidence-based home visiting services during pregnancy and to parents with young children up to kindergarten entry. States, territories, tribal entities, and in certain circumstances nonprofit organizations are eligible to receive funding through MIECHV and have the flexibility, within the parameters of the authorizing statute, to tailor the program to serve the specific needs of their communities.

The statewide needs assessment is a critical and foundational resource that assists awardees in identifying and understanding how to meet the needs of eligible families living in at-risk communities in their states.

After taking into consideration public comments in response to the 60-day Notice published in the **Federal Register** on April 24, 2018 (83 FR 17826), HRSA is proposing final revisions to the SIR guidance for the needs assessment update by making the following changes:

- Inserting references to the statutory requirements for each section of the guidance—specifically the sections of statute that require an assessment of state capacity to provide substance abuse treatment and counseling services.
- Increasing the burden estimate for respondents from 95.57 to 120 in response to comments that the original estimate was too low.

*Need and Proposed Use of the Information:* Congress, through enactment of the Social Security Act, Title V, Section 511 (42 U.S.C. 711), as amended, established the MIECHV Program. Section 50603 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) amended section 511(b)(1) of the Social Security Act, and requires that states review and update their statewide needs assessments (which may be separate from, but in coordination with, the Title V statewide

needs assessment) no later than October 1, 2020. The Bipartisan Budget Act of 2018 further establishes that conducting a MIECHV statewide needs assessment update is a condition of receiving Title V Maternal and Child Health Service (MCH) Block Grant funding; submission of the MIECHV needs assessment update in accordance with the guidance in the SIR will meet this requirement.

In response to the forthcoming SIR, states will be required to submit an updated statewide needs assessment that identifies all of the following information, as required by the MIECHV authorizing statute:

(1) Communities with concentrations of (a) premature birth, low-birth weight infants, and infant mortality, including infant death due to neglect, or other indicators of at-risk prenatal, maternal, newborn, or child health; (b) poverty; (c) crime; (d) domestic violence; (e) high rates of high-school drop-outs; (f) substance abuse; (g) unemployment; or (h) child maltreatment.

(2) The quality and capacity of existing programs or initiatives for early childhood home visitation in the state including: The number and types of individuals and families who are receiving services under such programs or initiatives; the gaps in early childhood home visitation in the state; and the extent to which such programs or initiatives are meeting the needs of eligible families.

(3) The state's capacity for providing substance abuse treatment and counseling services to individuals and families in need of such treatment or services.

The forthcoming SIR will provide further guidance to states in updating their statewide needs assessments and submitting the required information to HRSA. States that have elected not to apply or be awarded MIECHV funds are encouraged to work with nonprofit organizations that have received awards to provide MIECHV services within the state and indicate whether they will submit their needs assessments directly or through the nonprofit organization awardee. Nonprofit awardees will need to provide documentation to demonstrate that they have been authorized or requested by the state in which they provide services to submit a needs assessment on behalf of the state. Documentation, such as a letter, may come from a state's Title V agency; an other health, education or human services state agency; or the governor's office.

HRSA, states, and nonprofits providing MIECHV services within states will use the information collected through the needs assessment update to reaffirm the provision of MIECHV home visiting services in at-risk communities. The information will also be used to support program planning, improvement, and decision-making. The purpose of updating the statewide needs assessments is for awardees to gather more recent information on community needs and ensure that MIECHV programs are being operated in areas of high need. However, the requirement for such an update should not be construed as requiring moving MIECHV-funded home visiting programs, defunding of programs for the sole purpose of moving services to other communities, or otherwise disrupting existing home visiting programs, their relationships in the community, and their services to eligible families. The statutory requiremenets of a needs assessment update also apply to territory awardees, but this ICR does not include guidance, nor a burden estimate, for these awardees. Recognizing potential challenges related to the availability of population health data for the territories, a separate SIR will provide guidance on the needs assessment update to territories eligible to apply for MIECHV funds.

*Likely Respondents:* MIECHV Program Awardees that are states, territories, and, where applicable, nonprofit organizations providing services within states.

*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 and supporting materials; to collect and analyze data; engage with stakeholders and coordinate with state level partners; and to draft and submit the report. The table below summarizes the total annual burden hours estimated for this SIR.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

| Instrument | Number of respondents | Number of responses per respondent | Total responses | Average burden hours per response | Total burden hours |
|---|---|---|---|---|---|
| Maternal, Infant, and Early Childhood Home Visiting Program Statewide Needs Assessment Update | 51 | 1 | 51 | 120 | 6,120 |
| Total | 51 | | 51 | | 6,120 |

**Amy P. McNulty,**

*Acting Director, Division of the Executive Secretariat.*

[FR Doc. 2018–17972 Filed 8–20–18; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

**Project: Government Performance and Results Act (GPRA) Client/Participant Outcomes Measure—(OMB No. 0930–0208)—Revision**

SAMHSA is requesting approval to add 13 new questions to its existing CSAT Client-level GPRA instrument. Grantees will only be required to answer no more than four additional questions, per CSAT grant awarded, in addition to the other questions on the instrument. Currently, the information collected from this instrument is entered and stored in SAMHSA's Performance