

manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2024-N-3609 for “Development of an Enhanced Systematic Process for the Food and Drug Administration’s Post-Market Assessment of Chemicals in Food; Public Meeting; Extension of the Comment Period.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and 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.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

www.govinfo.gov/content/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, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Keronica Richardson, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2371.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 12, 2024, we published a notice announcing a public meeting entitled “Development of an Enhanced Systematic Process for FDA’s Post-Market Assessment of Chemicals in Food.” The notice explained that the public meeting would address a variety of topics related to development of an enhanced systematic process for FDA’s post-market assessment of chemicals in food, including:

- Principles for the post-market assessment process,
- Steps in the post-market assessment process,
- Prioritizing chemicals for post-market assessment, and
- Engaging stakeholders throughout the post-market assessment process (89 FR 65633 at 65635). We also provided an opportunity for public comment during the meeting. The docket for public comments was scheduled to close on December 6, 2024.

On September 25, 2024, we hosted the public meeting at the FDA White Oak Campus. A transcript of the meeting is available at <https://www.fda.gov/media/182622/download?attachment>.

We have received a request for a 60-day extension of the comment period. In general, the request explained that trade associations representing various parts of the food supply chain faced significant challenges to providing comment by December 6, 2024, and noted that the comment period overlapped with the holiday season and other FDA initiatives.

We have considered the requests and are extending the comment period until January 21, 2025. We believe that the extension will allow adequate time for interested persons to submit comments.

Dated: November 13, 2024.

Kimberlee Trzeciak,
Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024-27289 Filed 11-20-24; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Inclusion of Terrain Factors in the Definition of Rural Area for Federal Office of Rural Health Policy Grants

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

ACTION: Final notice.

SUMMARY: HRSA’s Federal Office of Rural Health Policy (FORHP) is modifying the definition of “rural area” for the purposes of determining geographic eligibility to apply for or receive services funded by FORHP’s rural health grants. With a data-driven methodology, this update to the definition of rural area will integrate the new Road Ruggedness Score (RRS) released in 2023 by the Economic Research Service of the U.S. Department of Agriculture. This notice responds to comments received on proposed modifications to HRSA’s FORHP definition published in the **Federal Register** on April 26, 2024.

DATES: All changes will go into effect as of November 21, 2024, and will apply to FORHP’s Notices of Funding Opportunity released in Fiscal Year (FY) 2025 and future years.

FOR FURTHER INFORMATION CONTACT: Greta Stuhlsatz, Statistician, Policy Research Division, FORHP, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; (301) 443-0835 and ruralpolicy@hrsa.gov.

SUPPLEMENTARY INFORMATION: This notice updates the definition of rural area used for HRSA’s FORHP rural health grants programs. HRSA published a notice in the **Federal Register** on April 26, 2024, seeking public comment on proposed modifications to the definition of rural area for the purposes of determining eligibility for its rural health grant programs (89 FR 32451). HRSA proposed a data-driven methodology to update the definition of rural area by integrating the new RRS released in 2023 by the Economic Research Service of the U.S. Department of Agriculture. The RRS characterizes topographic variability, or ruggedness, of roads. A

technical clarification was also proposed in response to terminology changes by the U.S. Census Bureau. This notice includes a summary of responses to the public comments received.

Background

In FY 2024, HRSA's FORHP considered the following areas to be rural for purposes of FORHP's grant programs:

- (1) All non-metro counties,
- (2) All outlying metro counties without an Urbanized Area,
- (3) All metro census tracts with RUCA codes 4–10, and
- (4) Metro census tracts of at least 400 square miles in area with population density of 35 or less per square mile with RUCA codes 2–3.

In the **Federal Register** notice published April 26, 2024, HRSA proposed modifying its existing FORHP rural definition by adding census tracts of at least 20 square miles in area in metropolitan counties with RRS 5 (highly rugged) and RUCA code 2 or 3 to FORHP's definition of rural area. Only census tracts that meet all criteria—RRS 5 and RUCA 2 or 3 with an area of 20 or more square miles—would be newly eligible under the proposed update.

In addition to the proposed rugged terrain update, in HRSA's notice, FORHP provided a technical clarification in response to the U.S. Census Bureau's 2020 terminology changes removing urban clusters and urbanized areas. FORHP's FY 2024 definition excludes outlying metropolitan counties with an *Urbanized Area* while the U.S. Census Bureau no longer uses this terminology. To retain the distinction in FORHP's definition of rural area between urban areas with population of 50,000 or more and urban areas with a population less than 50,000, FORHP will identify and categorize urban areas based on population size. With this technical clarification, HRSA is updating FORHP's rural definition by striking the phrase "outlying metropolitan counties without an urbanized area." and replacing it with "outlying metropolitan counties with no population from an urban area of 50,000 or more people."

Summary of Comments and Responses

HRSA received 27 comments in response to the notice published April 26, 2024. Comments responded to both the proposed expansion of the definition of rural area and the technical clarification following the removal of urbanized areas and urban clusters by the U.S. Census Bureau. Most of the

comments received (26) were in full or partial support of either or both components of the change—the technical clarification and the expanded eligibility criteria to include rugged terrain factors. One comment was out of scope of this proposal.

Technical Clarification in Response to Census Terminology Changes

Comment: All comments that referenced the technical clarification to retain the distinction between urban areas with population over and under 50,000 in FORHP's definition of rural area were supportive of changing FORHP's definition to remove reference to Urbanized Areas and instead categorize urban areas based on population size.

Response: We thank the commenters for their support. After consideration of the comments received, we are implementing the technical clarification as proposed.

Adding Rugged Terrain Data to the Definition of Rural Area

Many comments were in favor of expanding the definition to include rugged terrain using the RRS developed by the Economic Research Service. We thank the commenters for their support.

Some comments suggested modifications or alternatives to the proposed change.

Comment: Some commenters suggested expanding the definition by including small counties with a high density of census tracts that are RRS 3, 4, and 5. Further, commenters suggested we specifically include all census tracts in a county that are greater than 20 square miles in area with RUCA codes of 2 or 3 if the county has 12 or fewer census tracts and over 80 percent of census tracts within the county are RRS 3–5.

Response: Including census tracts greater than 20 square miles with RUCA of 2–3 within metropolitan counties is consistent with the proposed change. The additional county-level criteria suggested—limiting the expansion to only counties with 12 or fewer census tracts and calculating the percentage of tracts per county with RRS 3 through 5—would not achieve the objective of the programs or be operationally feasible for the purposes of grantmaking. First, aggregating measures defined at the census tract level to create a single county-level estimate would not further FORHP's goal of identifying rural census tracts within metropolitan counties using the individual characteristics and data from those tracts to understand local conditions. Second, this proposal could introduce

state and regional inconsistencies because county sizes vary widely across the United States. In effect, this proposal would treat counties and states differently based primarily on their geographic size. Finally, the complexity of the proposed calculation is inconsistent with FORHP's intent to use clear, consistent, and data-driven criteria that can be easily understood and applied nationwide. For these reasons, we are finalizing the language as proposed.

Comment: A commenter suggested including census tracts with RRS 3 (slightly rugged) and RRS 4 (moderately rugged) in addition to the proposed RRS 5 tracts in the expanded rural definition.

Response: Including census tracts with RRS 5 that meet the proposed criteria for size and RUCA code adds 84 census tracts and 305,000 people. RRS 3 and RRS 4 includes census tracts in and around major urban areas such as Nashville, Tennessee, and census tracts in northern New Jersey. Given their lesser topographic variation and their close proximity to major urban hubs and urban amenities, we are not considering these RRS 3 and RRS 4 tracts for the purpose of our rural area definition and are finalizing as proposed.

Comment: A commenter suggested that Hawaii should be exempt from the requirement that census tracts with rugged terrain be at least 20 square miles in area due to the unique geography of the state.

Response: Small census tracts are common in densely populated areas in all parts of the United States. Applying a different standard in one state would not further FORHP's goal of using clear, data-driven criteria that can be consistently applied nationwide to identify rural areas. For these reasons, we are not adopting this suggestion.

Comment: Some commenters suggested that road ruggedness should be used as a factor for defining rural areas, but FORHP should explore, for the future, alternative approaches for identification of mountainous roads.

Response: We thank the commenters for their support for using road ruggedness. FORHP continuously monitors ongoing national research and analysis efforts related to developing new geographic data sources and defining rural areas. We welcome suggestions for alternative data sets that are national in scope and that would identify mountainous roads more accurately. As new methods and data become available, FORHP may consider updating the definition.

Comment: A commenter suggested that the definition should focus on

service area rather than specific addresses of providers.

Response: The purpose of FORHP's rural definition is to delineate the land area of the United States as rural or non-rural. The areas identified as rural by this definition may include both service areas and specific provider addresses.

After consideration of the public comments received, HRSA is implementing the rugged terrain inclusion in the definition of rural area as proposed. FORHP is making this change consistent with its program authority to award grants to support rural health and rural health care services.

Updated Definition of Rural Area

HRSA is updating FORHP's rural definition to include geographic areas meeting any one of the following criteria:

- (1) Non-metropolitan counties
- (2) Outlying metropolitan counties with no population from an urban area of 50,000 or more people
- (3) Census tracts with RUCA codes 4–10 in metropolitan counties
- (4) Census tracts of at least 400 square miles in area with population density of 35 or less per square mile with RUCA codes 2–3 in metropolitan counties
- (5) Census tracts with RRS 5 and RUCA codes 2–3 that are at least 20 square miles in area in metropolitan counties

The changes will go into effect as of November 21, 2024. These changes will apply to FORHP's Notices of Funding Opportunity for FY 2025 and future years for programs that require funded activities and services be provided in rural areas, as defined by HRSA. FORHP will ensure information about the updated rural definition is available to the public on the HRSA website and in funding opportunities. These changes reflect FORHP's desire to accurately identify rural areas using a data-driven methodology that relies on established geographic identifiers and standard, national-level data sources.

Impact

Incorporating rugged terrain data into the definition of rural area using the adopted method adds 84 census tracts and approximately 305,000 people to the 60.8 million people living in FORHP-designated rural areas. This is an increase of 0.5 percent in the total number of people living in rural areas. Table 1 show the number of newly rural census tracts by state.

TABLE 1—NUMBER OF NEWLY RURAL CENSUS TRACTS BY STATE

State	Number of tracts
CA	24
OR	16
NC	12
WA	9
TN	7
CO	6
WV	6
MT	2
AK	1
MD	1
Total	84

Note: Table shows the number of newly rural census tracts with RRS 5 and RUCA codes 2–3 that are at least 20 square miles in area in metropolitan counties. Data in this table are based on 2010 census tract geographies and 2020 metropolitan county delineations. For a complete list of impacted census tracts see <https://www.hrsa.gov/rural-health/about-us/what-is-rural/data-files>.

Carole Johnson,
Administrator.

[FR Doc. 2024–27133 Filed 11–20–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 1009 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 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 Inherited Disease Research Access Committee.

Date: January 10, 2025.

Time: 11:30 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Room 3172, Bethesda, MD 20892 (Virtual).

Contact Person: Barbara J. Thomas, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, National Institutes of Health, 6700B

Rockledge Drive, Room 3172, Bethesda, MD 20892, (301) 402–8837, barbara.thomas@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: November 15, 2024.

David W. Freeman,
Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–27167 Filed 11–20–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning the opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer at (240) 276–0361.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Minority AIDS Initiative: Substance Use Disorder Prevention and Treatment Pilot Program (MAI PT Pilot) Data Collection Instruments

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention (CSAP) and Center for Substance Abuse Treatment (CSAT) are requesting approval from the Office of Management and Budget (OMB) to monitor the Minority AIDS Initiative: Substance Use Disorder Prevention and Treatment Pilot Program (MAI PT Pilot)