DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Response to Comments on Revised Geographic Eligibility for Federal Office of Rural Health Policy Grants

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

ACTION: Revised definition of rural area; final response to comments.

SUMMARY: HRSA's Federal Office of Rural Health Policy (FORHP) is modifying the definition it uses of rural for the determination of geographic areas eligible to apply for or receive services funded by FORHP's rural health grants. This notice revises the definition of rural and responds to comments received on proposed modifications to how FORHP designates areas to be eligible for rural health grant programs published in the **Federal Register** on September 23, 2020. After consideration of the public comments received, FORHP is adding Metropolitan Statistical Area (MSA) counties that contain no Urbanized Area (UA) population to the areas eligible for rural health grant programs.

DATES: All proposed changes will go into effect for new rural health grant opportunities anticipated to start in Fiscal Year 2022.

FOR FURTHER INFORMATION CONTACT: Steve Hirsch, Public Health Analyst, FORHP, HRSA, 5600 Fishers Lane, Mailstop 17W59D, Rockville, MD 20857. Phone: (301) 443–0835. Email: *ruralpolicy@hrsa.gov.*

SUPPLEMENTARY INFORMATION: FORHP published a notice in the **Federal Register** on September 23, 2020, (85 FR 59806) seeking public comment on proposed modifications to how it designates areas eligible for its rural health grant programs. FORHP proposed a data-driven methodology connected to existing geographic identifiers that could be applied nationally and be applicable to the wide variation in rural areas across the U.S.

FORHP uses the Office of Management and Budget (OMB)'s list of counties designated as part of a MSA as the basis for determining eligibility to apply for, or receive services funded by, its rural health grant programs. Currently, all areas within non-metro counties (both Micropolitan counties and counties with neither designation) are considered rural and eligible for rural health grants. FORHP also designates census tracts within MSAs as rural for grant purposes using Rural-Urban Commuting Area (RUCA) codes from the Economic Research Service (ERS) of the U.S. Department of Agriculture (USDA). These include all census tracts inside MSAs with RUCA codes 4–10 and 132 large area census tracts with RUCA codes 2 and 3. The 132 MSA census tracts with RUCA codes 2–3 are at least 400 square miles in area with a population density of no more than 35 people per square mile. Information regarding FORHP's designation of rural is publicly available on its website at: *https://www.hrsa.gov/rural-health/about-us/definition/index.html* and *https://data.hrsa.gov/tools/rural-health.*

In the **Federal Register** notice published in September 2020, FORHP proposed modifying its existing rural definition by adding outlying MSA counties with no UA population to its list of areas eligible to apply for and receive services funded by FORHP's rural health grants. UAs are defined by the Census Bureau as densely settled areas with a total population of at least 50,000 people.

FORHP received 67 comments in response to the **Federal Register** notice. Following is a summary of the comments received.

Over three quarters of the comments received supported the proposal to add outlying MSA counties with no UA population to the list of areas eligible for rural health grants. While most comments supported the proposal, several advised against adoption of the proposal. There were also several commenters who neither supported nor opposed the proposal.

The comments in favor of the proposal agreed with FORHP that proximity to a Metropolitan area does not mean a county is not rural in character and that shifts in employment and job creation have drawn people to commute to jobs in MSAs even though they still live in rural areas. Many commenters noted that FORHP's proposal appropriately identified populations that were rural in character and did not include areas or populations that were not rural in character.

Those who opposed the proposed modification did so for a variety of reasons. These included:

1. There are limited resources currently available for rural populations. Increasing the number of people and areas eligible will dilute the resources available.

2. The proposed modification does not include some areas that used to be considered rural, and still should be, but are now part of MSAs.

3. The proposal is too limited and should more expansively define what is rural.

4. The proposal, and the current definition of what is eligible for rural health grants, is too expansive and includes areas that are not truly rural.

5. Determination of need in rural areas should include whether areas are ''underserved,'' alternatively, the determination should factor in unemployment as another criteria.

Response to Comment 1: FORHP understands commenters concerns that expanding the number of areas eligible to apply for rural health grants has the potential to dilute available resources for existing rural areas. At the same time, it is important to identify the entire rural population as objectively and accurately as possible so that resource allocation decisions can be based on complete and accurate information. The modification is intended to more accurately identify rural populations within MSAs.

Response to Comment 2: After every Census, there is a process to identify areas where population has increased or decreased. Urban Clusters, which have increased in population above the 49,999 limit, are re-designated as UA and, vice versa, some UA may lose population and be re-designated as Urban Clusters. FORHP's intent, with the use of RUCA codes and this proposed modification for counties with no UA population, is to correctly identify rural populations inside of MSAs.

Response to Comment 3: FORHP is proposing clear, quantitative criteria using nationally available data for an expansion of areas eligible for rural health grants. FORHP has not identified clear, quantitative criteria beyond what was proposed.

Response to Comment 4: FORHP will continue to use the best available means it can to define rural areas.

Response to Comment 5: FORHP is modifying its identification of rural areas with this notice, consistent with its program authority to award grants to support rural health and rural health care services. While rural areas are frequently underserved and may experience shortages of health care providers, rurality and underservice are not the same thing. Unemployment is also a factor that does not determine rurality since a rural area could have high or low unemployment. Both could be used as factor in grant awards, given programmatic goals, but do not indicate rurality.

Many of the commenters, both those who supported and those who opposed the proposed FORHP modifications,

also suggested further modifications or adjustments to the way FORHP defines rural areas.

Comment: The most common suggestion was that FORHP identify difficult and mountainous terrain because travel on roads through such terrain is more difficult and time-consuming.

Response to Comment: FORHP recognizes that travel in difficult and mountainous terrain, along with distance, are often barriers to access to health care.

The ERS of U.S. Department of Agriculture was charged with researching the feasibility of identifying census tracts with difficult and mountainous terrain in Senate Report 116–110—Agriculture, Rural Development, Food and Drug Administration, and related Agencies Appropriations Bill, 2020. ERS produces the RUCA codes that FORHP uses to identify rural areas insides MSAs. ERS has greater experience and resources to analyze geography than FORHP does. If ERS does add identifiers for difficult and mountainous terrain to the RUCA codes, FORHP will examine the feasibility of using this information to designate rural census tracts in MSAs.

Comment: Many commenters suggested specific Metropolitan counties by name that they believed should be designated as rural.

Response to Comment: Consistent with other federal geographic standards, FORHP seeks only to use appropriate objective data to assess a geographic unit to determine whether a place meets those standards. FORHP cannot define individual counties as rural without having clear, data-driven criteria that can be equitably applied.

Comment: Many commenters suggested that FORHP consider expanding eligibility to urban health centers that primarily serve rural populations.

Response to Comment: FORHP implemented this suggestion after the Coronavirus Aid, Relief, and Economic Security Act (the CARES ACT, Pub. L. 116–136) reauthorized the Rural Health Care Services Outreach, Rural Health Network Development, and Small Health Care Provider Quality Improvement grant programs created by Section 330A of the Public Health Service Act (42 U.S.C. 254c). The CARES Act changed the statutory authority for Rural Health Care Services Outreach and Rural Health Network Development grants and expanded eligibility to allow urban entities to apply as the lead applicant for these rural health grants as long as they serve eligible rural populations.

Comment: Some commenters suggested that FORHP should accept state government-designated rural areas for the purpose of eligibility for rural health grant programs.

Response to Comment: FORHP understands and supports the right of states to develop definitions of rural that meet their specific needs. In determining eligibility for a federal grant program that is national in scope, the challenge for FORHP is having consistent and objective standards that can be applied consistently across the entire country. For that reason, FORHP uses quantitative standards that can be applied nationally and consistently in an administratively efficient manner.

Comment: Some commenters suggested that FORHP allow individual counties to request designations as rural.

Response to Comment: FORHP applies consistent quantitative standards to identify rural areas and populations across the nation as a whole. An exception process for individual counties would yield inconsistent results.

Comment: Commenters suggested that all providers with specific certifications or special payment designations (*e.g.,* Rural Health Clinics, Critical Access Hospitals, etc.) from the Centers for Medicare & Medicaid Services (CMS) should be designated as eligible for rural health grant programs and that FORHP should coordinate the definition of rural with CMS.

Response to Comment: Many of the providers identified as ''rural'' by CMS are classified using different standards that are specific to each special designation. In addition, some designated providers are no longer located in rural areas due to population growth over time. They have maintained their status due to reclassification or grandfathering provisions specific to those certification and payment programs. In contrast, the purpose of FORHP grants is to provide services to the rural population, as determined by a consistent, quantitative standard. FORHP notes that hospitals or clinics that have the CMS rural designation can still apply for FORHP rural health grant funding as long as they propose to serve an eligible rural population. This change was part of the recent re-authorization of the Section 330A programs described above. FORHP believes this change will address some of the concerns raised by commenters.

Comment: Several commenters suggested grandfathering providers, as legacy rural sites of care which would enable those organizations to apply for rural health grants even if they were no longer located in a rural area.

Response to Comment: This comment is similar, but not precisely the same as the earlier comment that FORHP should accept all providers with specific certifications or special payment designations from CMS as eligible for rural health grants. The change in statutory authority for the Section 330A programs will allow these providers to continue to apply for rural health grants as long as they continue to serve rural populations. Identifying and tracking legacy rural sites of care would be administratively unworkable and is not needed to target services to rural populations.

Comment: Several commenters suggested that FORHP remove incarcerated people from the total population that makes up the UA core of a MSA in cases where the UA population would fall below the floor of 50,000.

Response to Comment: FORHP has not identified a data source to consistently determine the populations of incarcerated people within the UA boundaries. Without a standard, national data source, FORHP cannot calculate the number of incarcerated people for every UA and determine whether removal of this population from a UA core would reduce the total population below 50,000. In addition, prison populations can fluctuate year to year and there are administrative challenges in validating data from local sources.

Comment: Several commenters suggested that FORHP remove college students from UA population totals.

Response to Comment: As with the population of incarcerated people mentioned above, FORHP does not have a national data source to identify the student population of an UA. Students are also able to access health care resources in the community. Without a standard, national data source, FORHP cannot calculate the number of college students for every UA and determine whether removal of this population from a UA core would reduce the total population below 50,000. In addition, there are administrative challenges in validating data from local sources.

Comment: Several commenters suggested that if FORHP does adopt the proposed modification and increases the number of people eligible to be served by rural health grants, FORHP should increase the funding available for grants.

Response to Comment: The level of resources available for any federal program is determined by Congress.

Comment: Several Tribal organizations wrote comments objecting to the modification. They suggested that all Tribal lands be defined as rural and that funds be set aside solely for awards to Tribal health providers.

Response to Comment: The statutory authority for rural health grant programs directs services at rural areas and populations. FORHP understands the unique challenges faced by Tribal entities. Rural health grants can be and have been awarded to Tribal organizations located in rural areas. With the changes in the authorization for 330A programs, urban Tribal providers can also apply for rural health grants to serve rural populations. FORHP cannot change rural health funding to direct it to urban populations, even if they are underserved, or specify funding set-asides for Tribal organizations.

Comment: Different commenters suggested that FORHP use a combination of population density, travel time or distance, geographic isolation, and access to resources to designate rural areas, or that FORHP use Frontier and Remote Area (FAR) Codes to determine rurality.

Response to Comment: Commenters did not suggest data sources that would combine population density, travel time or distance, geographic isolation, and access to resources to provide a consistent, nationally standard definition of rural areas. FAR Codes utilize population density and travel time to designate different levels of ''frontier'' or remoteness. However, much of the rural U.S. that is currently eligible for rural health grants is not designated as frontier and remote and would lose eligibility if only FAR codes were used.

FORHP thanks the public for their comments. After consideration of the public comments we received, FORHP is implementing the modification as proposed to expand its list of rural areas. FORHP will add MSA counties that contain no UA population to the areas eligible for rural health grant programs. Using the March 2020 update of MSA delineations released by OMB, 295 counties will meet this criteria as outlying MSA counties with no UA population. The expanded eligibility will go into effect for new rural health grants awarded in fiscal year 2022. FORHP will ensure information about the expanded eligibility is available to the public and update the Rural Health Grants Eligibility Analyzer at *https://data.hrsa.gov/tools/rural-health* for fiscal year 2022 funding opportunities. These changes reflect FORHP's desire to accurately identify areas that are rural in character using a data-driven methodology that relies on existing geographic identifiers and utilizes standard, national level data sources.

Thomas J. Engels,

Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. FDA–2020–N–2246]

Notice That Persons That Entered the Over-the-Counter Drug Market To Supply Hand Sanitizer During the COVID–19 Public Health Emergency Are Not Subject to the Over-the-Counter Drug Monograph Facility Fee

AGENCY: Food and Drug Administration (FDA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services is issuing this Notice to clarify that persons that entered into the over-the-counter drug industry for the first time in order to supply hand sanitizers during the COVID–19 Public Health Emergency are not persons subject to the facility fee the Secretary is authorized to collect under section 744M of the Food, Drug, and Cosmetic Act.

DATES: January 12, 2021.

FOR FURTHER INFORMATION CONTACT: David Haas, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61075, Beltsville, MD 20705–4304, 240–402 4585.

SUPPLEMENTARY INFORMATION: On December 29, 2020, FDA published a Notice in the **Federal Register** entitled *Fee Rates Under the Over-the-Counter Monograph User Fee Program for Fiscal Year 2021.* 85 FR 85646. The Department since withdrew that Notice because it was not approved by the Secretary. For the reasons provided below, the Department is clarifying that persons that entered the over-the-counter drug market to supply hand sanitizer products in response to the COVID–19 Public Health Emergency are not subject to the facility fee the Secretary is authorized to collect under section 744M of the Food, Drug, and Cosmetic Act (FD&C Act).

In March 2020, FDA issued a temporary policy to enable increased production of alcohol-based hand sanitizers.[1] The agency acknowledged ''that some consumers and health care personnel are currently experiencing difficulties accessing alcohol-based hand sanitizers,'' and that some were relying on home-made hand sanitizers as a result.[2] FDA issued the guidance in response to requests from ''certain entities that are not currently regulated by FDA as drug manufacturers'' that nevertheless rose up to meet this public health need.[3] FDA stated it ''does not intend to take action against firms that'' produce hand sanitizer products during the COVID–19 Public Health Emergency, provided the firm's activities are consistent with the guidance.[4]

The guidance, which FDA amended after the Coronavirus Aid, Relief, and Economic Security Act (''CARES Act''), Public Law 116–136, 134 Stat. 281 (March 27, 2020) became law, contains no mention of user or facility fees. FDA's website on Hand Sanitizers and COVID–19, contains a sub-bullet under the link to the guidance announcing that ''the facility fee applies to all OTC hand sanitizer manufacturers registered with FDA, including facilities that manufacture or process hand sanitizer products under this temporary policy,'' but that language was added about the same time as the aforementioned withdrawn Notice was published in the **Federal Register**.[5] Entities that began producing hand sanitizers in reliance on the guidance were understandably surprised when FDA contacted them to collect an establishment fee in excess of $14,000.[6]

FDA's purported authority for these facility fees comes from the CARES Act. In section 3862 of the CARES Act, Congress provided the Secretary with the authority to assess user and facility fees from ''each person that owns a facility identified as an OTC drug monograph facility on December 31 of the fiscal year or at any time during the preceding 12-month period.'' FD&C Act 744M(a)(1)(A), 21 U.S.C. 379j–

[1] FDA, Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID–19) Guidance for Industry (Mar. 2020; updated Aug. 7, 2020).

[2] *Id.* at 3.

[3] *Id.*

[4] *Id.*

[5] An archived version of the website shows the language at issue was not on the website as late as December 29, 2020. See: *https://web.archive.org/web/20201229105739/https://www.fda.gov/drugs/coronavirus-covid-19-drugs/hand-sanitizers-covid-19.*

[6] This surprise, coupled with the guidance's silence on facility fees, raises reliance interests concerns under the Supreme Court's decision in *Department of Homeland Security* v. *Regents of the University of California,* 140 S. Ct. 1891 (2020).