

changed by the CARES Act.⁷ We are aware that there have been scientific developments in the time since the proposed rule was issued including, among other things, the publication of two new studies on the absorption of sunscreen active ingredients,⁸ both of which reinforced the need for the sunscreen ingredient data requested in our proposed rule (and in the proposed order). The comment period on this proposed order affords an opportunity for the public to submit information that has become available since the closure of the comment period on the 2019 Proposed Rule. This includes information that has become available regarding the eight sunscreen active ingredients, identified above, that were the subject of timely requests for deferral in order to conduct studies to generate data first identified as lacking in the 2019 Proposed Rule. We note that if at any time the available evidence becomes sufficient to resolve the uncertainty as to the GRASE status of a sunscreen containing any of these ingredients, FDA intends to proceed to a revised final order reflecting our conclusion as to its status. However, if at the close of the comment period on this proposed order, the available data do not resolve the outstanding questions about each of these ingredients, but the Agency has received satisfactory indication of timely and diligent progress on the necessary studies for a specific ingredient, FDA would be prepared to initially defer issuance of a revised final order on the GRASE status of sunscreens containing that particular active ingredient. Such a deferral would be for a period of not more than 1 year, with a possibility of extension depending on further satisfactory progress with the studies. However, if, in FDA's judgment, studies for any active ingredient do not appear to be proceeding in a timely manner or otherwise do not appear to be productive, the Agency expects that it will proceed to a revised final order on sunscreens containing such particular ingredient after this initial deferral.

As noted above, the Agency also received a significant number of comments to the public docket during the previous public comment period on the proposals described in the 2019 Proposed Rule, which we continue to

review. FDA will consider all comments that were submitted to the public docket for the 2019 Proposed Rule within its comment period to be constructively submitted as comments on the proposed order being issued today. To enable the Agency to review and address these comments (and future comments that may be submitted on this proposed order) as expeditiously as possible, we request that commenters do *not* resubmit comments on this proposed order previously submitted on the proposed rule. FDA believes that this approach will allow us to efficiently consider public input as the Agency assesses the appropriate regulatory requirements for nonprescription sunscreens marketed without approved new drug applications.

We emphasize in the proposed order, and here, that the proposed order does not represent a conclusion by FDA that the sunscreen active ingredients included in the 1999 Final Monograph, but proposed in the order as needing additional data, are unsafe for use in sunscreens. Rather, we are requesting additional information on these ingredients so that we can evaluate their GRASE status in light of changed conditions, including substantially increased sunscreen usage and exposure and evolving information about the potential risks associated with these products since originally evaluated. As in the 2019 Proposed Rule, this proposed order also advances proposals addressing the other conditions of use for sunscreen drug products marketed without an approved application, including broad spectrum protection, maximum SPF requirements, dosage forms, labeling, final formulation testing and recordkeeping, sunscreen-insect repellent combinations, and more.

II. Paperwork Reduction Act of 1995

This proposed order is issued under section 505G(b) of the FD&C Act. Chapter 35 of title 44, United States Code does not apply to collections of information made under section 505G of the FD&C Act (see section 505G(o) of the FD&C Act).

III. Electronic Access

Persons may obtain the proposed order at the OTC Monographs@portal at <https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm> or at <https://www.regulations.gov>.

IV. References

The following references are on display with the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday

through Friday; these are not available electronically at <https://www.regulations.gov> as these references are copyright protected. Some may be available at the website address, if listed. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Matta, M.K., J. Florian, R. Zusterzeel et al., "Effect of Sunscreen Application on Plasma Concentration of Sunscreen Active Ingredients: A Randomized Clinical Trial," *Journal of the American Medical Association*, vol. 323(3), pp. 256–267, 2020 (available at <https://jamanetwork.com/journals/jama/fullarticle/2759002>), accessed August 12, 2021.
2. Matta, M.K., R. Zusterzeel, R.P. Nageswara Matta et al., "Effect of Sunscreen Application Under Maximal Use Conditions on Plasma Concentration of Sunscreen Active Ingredients: A Randomized Clinical Trial," *Journal of the American Medical Association*, vol. 321(21), pp. 2082–2091, 2019 (available at <https://jamanetwork.com/journals/jama/fullarticle/2733085>), accessed August 12, 2021.

Dated: September 21, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–20780 Filed 9–24–21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Criteria for Determining Maternity Care Health Professional Target Areas

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

ACTION: Request for public comment.

SUMMARY: In accordance with the requirements of the Public Health Service Act, HRSA, authorized by the Secretary of HHS, shall establish the criteria which will be used to determine maternity care health professional target areas (MCTAs) in existing primary care Health Professional Shortage Areas (HPSAs). This notice sets forth the proposed criteria which will be used to identify and score MCTAs.

DATES: Submit written comments no later than November 26, 2021.

ADDRESSES: Written comments should be submitted to SDMP@hrsa.gov.

FOR FURTHER INFORMATION CONTACT: Dr. Janelle McCutchen, Chief, Shortage Designation Branch, Division of Policy

⁷ See section 505G(k)(1) of the FD&C Act and 21 CFR 330.10(a)(4).

⁸ See "FDA in Brief: FDA Announces Results From Second Sunscreen Absorption Study," available at <https://www.fda.gov/news-events/fda-brief/fda-brief-fda-announces-results-second-sunscreen-absorption-study>, describing Matta, et al. (2020) (Ref. 1), as well as a prior pilot study (Matta, et al. 2019) (Ref. 2).

and Shortage Designation, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443-9156.

SUPPLEMENTARY INFORMATION: Section 332 of the Public Health Service Act, 42 U.S.C. 254e, provides that HRSA shall designate HPSAs based on criteria established by regulation. HPSAs are defined in section 332 to include (1) urban and rural geographic areas which HRSA determines have shortages of health professionals, (2) population groups with such shortages, and (3) public or private medical facilities or other public facilities with such shortages. The required regulations setting forth the criteria for designating HPSAs are codified at 42 CFR part 5.

Section 332(k)(1) provides that HRSA shall identify shortages of maternity care services “within health professional shortage areas.” Section 332(k)(1) further requires HRSA to identify MCTAs and distribute maternity care health professionals within HPSAs using the MCTAs so identified. HRSA must also collect and publish data in the **Federal Register** comparing the availability and need of maternity care health services in HPSAs and must seek input from relevant provider organizations and other stakeholders.

HRSA sought input regarding MCTA scoring from relevant stakeholders via a Request for Information issued in May 2020. HRSA received 24 comments from a variety of stakeholders, including State Primary Care Offices, Indian tribes, Federally Qualified Health Centers, and women’s health and public health advocacy groups. The comments addressed a wide range of maternity care concerns, including social determinants of health that impact maternal health outcomes, women’s access to prenatal care, prevalence of chronic disease, maternity care health professional provider types to be included in MCTAs, and the maternity care needs of women in rural areas and among tribes and Alaska natives. Several commenters also provided suggestions on data sources that HRSA could use to calculate MCTA scores.

HRSA has carefully reviewed and considered all of the feedback provided. HRSA proposes the following MCTA scoring criteria, which will be used to distribute certain currently eligible National Health Service Corps (NHSC) clinicians who provide maternity care services. This includes obstetrician gynecologists (OB/GYNs) and certified nurse midwives (CNMs). The statute does not expand discipline eligibility for participation in the NHSC to health

professionals who are not already eligible for the NHSC. *See* section 332(k)(1).

Approach for Determining Maternity Care Health Professional Target Areas of Greatest Shortage

A MCTA score will be generated for each primary care HPSA using the HPSA’s service area. The following six scoring criteria will be included in a composite scale that will be used to identify MCTAs with the greatest shortage of maternity care health professionals: (1) Ratio of females ages 15–44-to-full time equivalent maternity care health professional ratio; (2) percentage of females 15–44 with income at or below 200 percent of the federal poverty level (FPL); (3) travel time and distance to the nearest provider location with access to comprehensive maternity care services; (4) fertility rate; (5) the Social Vulnerability Index; and (6) four maternal health indicators (pre-pregnancy obesity, pre-pregnancy diabetes, pre-pregnancy hypertension, and prenatal care initiation in the first trimester). Each of these six criteria will be assigned a relative weight based on the significance of that criteria relative to all the others.

The weighted scores will be summed to develop a composite MCTA score ranging from zero to 25, with 25 indicating the greatest need for maternity care health professionals in the MCTA. Accordingly, the higher the composite score, the higher the degree of need for maternity care health services.

Score for Population-to-Full-Time-Equivalent Maternity Care Health Professional Ratio

HRSA is seeking public comment on the proposed approach to measuring the ratio of females ages 15–44-to-full time equivalent (FTE) maternity care health professional, as HRSA received overwhelmingly positive stakeholder feedback indicating that HRSA should consider the population-to-provider ratio as a component of the MCTA score. Accordingly, population-to-provider ratio will measure the number of women of childbearing age in the service area compared to the number of maternity care health professionals in the service area. The population-to-provider ratio continues to be a cornerstone in measuring the availability of primary care resources within a particular area. Based on the available literature and recommendations received, for purposes of MCTA scoring, women of childbearing age will be defined as

women between the ages of 15–44 years old and maternity care professionals will be defined as Obstetrician/ Gynecologists and Certified Nurse Midwives (CNMs).¹ A population-to-provider ratio of 1,500:1 will be used as a minimum requirement for a population to be considered reasonably served by Obstetrician/Gynecologists and CNMs.²

Based on comments received, research, and consultation with stakeholders, HRSA did not include General Surgeons, Anesthesiologists, Pediatricians, Doulas, and Lactation Specialists into the provider portion of the population-to-provider ratio for MCTA scoring, as these providers do not typically provide full-scope comprehensive maternity care. Additionally, HRSA considered including Family Medicine Physicians, Physician Assistants, Advance Practice Registered Nurses, and Registered Nurses who provide Women’s Health services or obstetric care into the provider portion of the population-to-provider ratio for MCTA scoring. With respect to Family Medicine Physicians, research shows that family medicine practitioners offering maternity care services has been in decline in recent years, and data demonstrating how much time these providers spend providing maternity care services is not readily available.

Rayburn, Petterson, and Phillips conducted an observational study from 2003 to 2010 in which they examined the proportion of Family Physicians who perform deliveries.³ The proportion of Family Physicians performing deliveries declined by 40.6 percent, from 17.0 percent in 2003 to 10.1 percent in 2009, with deliveries being more common in nonmetropolitan areas. The researchers concluded that the proportion of Family Physicians performing deliveries continues to decline with most delivering Family Physicians performing 25 or fewer deliveries per year. In another study, Makaroff, et al., evaluated factors that are contributing to the decline of Family

¹ Johantgen, M. et al. “Comparison of Labor and Delivery Care Provided by Certified Nurse-Midwives and Physicians: A Systematic Review, 1990 to 2008.” *Women’s Health Issues*, vol. 22, no. 1 (2012): e73–e81, doi: 10.1016/j.whi.2011.06.005.

² Rayburn, W.F. et al. “Distribution of American Congress of Obstetricians and Gynecologists Fellows and Junior Fellows in Practice in the United States.” *Obstet Gynecol*, vol. 119, no. 5 (2012): 1017, doi: 10.1097/AOG.0b013e31824cfe50.

³ Rayburn, William F., Stephen M. Petterson, and Robert L. Phillips. “Trends in Family Physicians Performing Deliveries, 2003–2010.” *Birth (Berkeley, Calif.)* 41.1 (2014): 26–32.

Physicians providing maternity care.⁴ Makaroff, et al. evaluated American Board of Family Medicine survey data collected from every family physician during application for the Maintenance of Certification Examination to determine the percentage of family physicians that provided maternity care from 2000 to 2010. This research team's findings are in line with the results of the research conducted by Rayburn, Petterson, and Phillips in that they also found that maternity care provision by family physicians declined from 23.3 percent in 2000 to 9.7 percent in 2010 (p <0.0001). Furthermore, in 2018, a study from Goldstein, et al. shows that the percentage of family practitioners offering low and high volume maternity care services continues to decline in both the United States and Canada and is now at less than 5 and 1 percent, respectively. These findings are based on data from the American Board of Family Medicine Examination

questionnaires. The data specifically showed that the number of family practitioners who offered high volume obstetric services has declined by 50 percent since 2009.⁵

Thus, while family physicians continue to play an important role in providing maternity care in many parts of the United States, there is a documented decline in the percentage of family physicians providing maternity care. HRSA recognizes the important contribution all of these professionals play in the delivery of obstetric care. However, as there is also not currently detailed nationwide data readily available outlining the number of hours individual providers provide these services, HRSA did not have an analytical basis for how to include them consistently. HRSA will continue to review the availability of these data points to determine if additional provider types (particularly Family Medicine Physicians, but also including

General Surgeons, Anesthesiologists, Pediatricians, Doulas, Lactation Specialists, Physician Assistants, Advance Practice Registered Nurses, and Registered Nurses who provide Women's Health services) may be incorporated into the MCTA scoring criteria in the future. HRSA is especially interested in recommendations for how to determine the amount of time Family Medicine Physicians spend providing maternity care services, as they may be the only providers of maternity services in areas with no OB/GYNs or CNMs. HRSA welcomes comments on how to incorporate these providers into future iterations of MCTA scoring, and any detailed nationwide data that may be available to do so.

HRSA is seeking feedback on the assigned point values in the distribution, which are proposed to be as follows:

Population-to-provider ratio	Points
Ratio ≥6,000:1, or No CNMs or OB-GYNs and Population (Pop) ≥500	5
6,000:1 >Ratio ≥5,000:1, or No CNMs or OB-GYNs and Pop ≥400	4
5,000:1 >Ratio ≥3,000:1, or No CNMs or OB-GYNs and Pop ≥300	3
3,000:1 >Ratio ≥2,000:1, or No CNMs or OB-GYNs and Pop ≥200	2
2,000:1 >Ratio ≥1,500:1, or No CNMs or OB-GYNs and Pop ≥100	1
Ratio <1,500:1, or No CNMs or OB-GYNs and Pop <100	0

Score for Percentage of Population With Income at or Below 200 Percent of the Federal Poverty Level

HRSA proposes to incorporate poverty data from the U.S. Census Bureau into the MCTA composite score, as the majority of commenters highlighted the disparities that women

living in poverty face in accessing necessary maternity health services. The percentage of people living in the service area at or below 200 percent of the FPL will be used to score MCTAs, based on recommendations from commenters and poverty data from the U.S. Census Bureau. Maternal health

literature demonstrates a high correlation between low income, low health status, and poor maternal health outcomes.⁶

HRSA is seeking feedback on the assigned point values in the distribution, which are proposed as follows:

Population with income at or below 200% FPL ratio	Points
Percentage of population with income at or below 200% FPL ≥55%	6
55% >Percentage of population with income at or below 200% FPL ≥50%	5
50% >Percentage of population with income at or below 200% FPL ≥45%	4
45% >Percentage of population with income at or below 200% FPL ≥40%	3
40% >Percentage of population with income at or below 200% FPL ≥35%	2
35% >Percentage of population with income at or below 200% FPL ≥30%	1
Percentage of population with income at or below 200% FPL <30%	0

Score for Travel Distance/Time to Nearest Source of Accessible Care Outside of the MCTA

Several of the commenters highlighted the barriers in travel time and transportation that many women face in accessing maternity care

services, particularly in rural and underserved areas. In keeping with this feedback, HRSA will incorporate the travel time and distance to the Nearest Source of Care into the MCTA composite score. The Nearest Source of Care is defined as the closest provider

location where the residents of the area or designated population have access to comprehensive maternity care services. Scientific literature presented by the American Academy of Pediatrics Committee on Fetus and Newborn and the American College of Obstetricians

⁴ Makaroff, Laura A. et al. "Factors Influencing Family Physicians' Contribution to the Child Health Care Workforce." *Annals of family medicine* 12.5 (2014): 427-431.

⁵ Goldstein, Jessica, et al., "Supporting Family Physician Maternity Care Providers" *Family Medicine* 50:9 (2018).

⁶ Aftab., et al. "Effects of Poverty on Pregnant Women." *Department of Gynae and Obstetrics, Dow University of Health Sciences, Lyari General*

Hospital, Karachi, vol. 51, no.1 (2012). March of Dimes, "Nowhere to Go: Maternity Care Deserts Across the US," (2018), available at https://www.marchofdimers.org/materials/Nowhere_to_Go_Final.pdf.

and Gynecologists Committee on Obstetric Practice established that an individual's proximity to care can affect health outcomes.⁷ Specifically for

maternity care, the literature indicates that decision-to-incision time for emergency cesarean delivery is 30 minutes.⁸

HRSA is seeking public comment on the assigned point values in the distribution, which are proposed as follows:

Travel time and distance	Points
Time ≥105 min, or Distance ≥105 miles	6
105 min >Time ≥90 min or 105 miles > Distance ≥90 miles	5
90 min >Time ≥75 min, or 90 miles > Distance ≥75 miles	4
75 min >Time ≥60 min, or 75 miles > Distance ≥60 miles	3
60 min >Time ≥45 min, or 60 miles > Distance ≥45 miles	2
45 min >Time ≥30 min, or 45 miles > Distance ≥30 miles	1
Time <30 min, and Distance <30 miles	0

Score for Fertility Rate

HRSA proposes to include fertility rate as a criteria for the MCTA score to reflect the increased need for maternity care services among populations which

experience a higher rate of births. Women of childbearing age will be derived from the American Community Survey and births will be derived from the National Vital Statistics System.

HRSA is seeking public comment on the assigned point values in the distribution, which are proposed as follows:

Fertility rate	Points
Fertility Rate ≥90th Percentile	2
90th Percentile >Fertility Rate ≥50th Percentile	1
Fertility Rate <50th Percentile	0

Score for Social Vulnerability Index

Several MCTA commenters highlighted associations between adverse maternal health outcomes and non-clinical factors such as poverty, unemployment, lack of adequate housing and transportation, minority status, and English language proficiency. The Agency for Toxic Substances and Disease Registry's Geospatial Research, Analysis and Services Program within the Centers for Disease Control and Prevention (CDC) created databases to help emergency response planners and public health officials identify and map communities that will most likely need support before, during, and after a hazardous event. Per the CDC, Social Vulnerability refers to the resilience of communities when confronted by external hazards such as natural or human-caused disasters, or disease outbreaks.

One such database is the Social Vulnerability Index (SVI), which uses

U.S. Census data to determine the social vulnerability of every census tract based on the following four themes:

Socioeconomic status, household composition and disability, minority status and language, and housing type and transportation. Each tract receives a separate percentile ranking which is represented by a number between zero and one for each of the four themes, as well as an overall ranking. These themes take into account various factors ranging from educational attainment and unemployment to multi-unit structures and single parent households.

Public health literature supports the correlation between low English proficiency and late initiation of prenatal care as well as adverse perinatal outcomes due to lack of communication between the provider and patient.^{9 10} Currently, literature is not available that evaluates the use of the entire SVI to specifically quantify maternal health outcomes. However,

many of the individual factors within the SVI are known social determinants of health. Social determinants of health are the conditions in the environment in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. These social determinants of health as represented within the SVI, are critical in understanding external factors that affect the need for maternity care services.

A score for overall social vulnerability will be incorporated into the MCTA composite score to reflect the increased need for maternity care services among populations which experience a higher rate of social vulnerability using the CDC's SVI. HRSA is seeking public comment on the assigned point values in the distribution, which are proposed as follows:

Social Vulnerability Index	Points
Social Vulnerability ≥75th Percentile	2
75th Percentile > Social Vulnerability ≥50th Percentile	1
Social Vulnerability <50th Percentile	0

⁷ Kilpatrick, Sarah J., et al. *Guidelines for Perinatal Care*. 8th ed., American Academy of Pediatrics, 2017.

⁸ Roa, Lina et al., "Travel Time to Access Obstetric and Neonatal Care in the United States." *Obstetrics and Gynecology* (New York. 1953) vol. 136, no. 3 (2020): 610–612.

⁹ Pope, Charlene. "Addressing Limited English Proficiency and Disparities for Hispanic Postpartum Women." *Journal of Obstetric, Gynecologic & Neonatal Nursing*, vol. 34, no. 4, 2005, pp. 512–20. *Crossref*, doi:10.1177/0884217505278295.

¹⁰ Vinson, Abigail, et al. "131: Maternal Language, Severe Maternal Morbidity and Access to Prenatal

Care." *American Journal of Obstetrics and Gynecology*, vol. 222, no. 1, 2020, pp. S99–100. *Crossref*, doi:10.1016/j.ajog.2019.11.147.

Score for Maternal Health Indicators

Many of the comments HRSA received raised concerns about social determinants of health that have an impact on women’s health outcomes, not only during and after pregnancy, but also before and in between pregnancies. In order to address these concerns, HRSA is seeking public comment on the use of maternal health indicators as scoring criteria for MCTAs. MCTA scores will consider health indicators that are associated with poor maternal health outcomes by looking at various data points related to pre-pregnancy health status and when prenatal care began. Scores will consider pre-pregnancy obesity, diabetes, and hypertension, as well as whether prenatal care began in the first trimester, as these are all conditions which may require additional workforce capacity to adequately address community needs. Only women of childbearing age will be considered for these indicators. HRSA will use the National Vital Statistics

System as the data source to determine the sub-score for each of these four (4) maternal health indicators.

Public health literature demonstrates that higher rates of obesity, diabetes, or hypertension, and later onset of prenatal care are all associated with poorer maternal health outcomes and will help identify the need for additional health professionals. A 2018 Centers for Disease Control and Prevention report on preconception health surveillance identified priority indicators for adverse maternal health outcomes.¹¹ The study reviewed 50 preconception health indicators and prioritized those indicators that are most suitable for surveillance purposes. Weight, diabetes, and hypertension were all among the top 10 preconception health indicators recommended for surveillance.¹²

HRSA also considered incorporating maternal mortality data into the MCTA score. However, due to data suppression for privacy reasons, this data is not readily available publicly or to HRSA below the state level. As both HPSAs

and MCTAs are designed to be able to provide meaningful differentiation of need between communities at a local level, HRSA decided not to incorporate maternal mortality data at this time. If this data eventually becomes available to HRSA at the county level or below, HRSA may include it in future MCTA score calculation.

HRSA is seeking public comment on the proposed criteria and point scale distributions below. Service areas may receive one point each for meeting the criteria.

• *Pre-Pregnancy Obesity*

Pre-pregnancy obesity is defined as having a Body Mass Index of 30 or higher. One point will be awarded if the prevalence of pre-pregnancy obesity in the area is greater than or equal to the 75th percentile among all counties in the United States. If the prevalence of pre-pregnancy obesity in the area is less than the 75th percentile among all counties, zero points will be awarded.

Pre-pregnancy obesity	Points
Prevalence of pre-pregnancy obesity ≥75th percentile	1
Prevalence of pre-pregnancy obesity <75th percentile	0

• *Pre-Pregnancy Diabetes*

One point will be awarded if the prevalence of pre-pregnancy diabetes in

the area is greater than or equal to the 75th percentile among all counties in the United States. If the prevalence of

pre-pregnancy diabetes in the area is less than the 75th percentile among all counties, zero points will be awarded.

Pre-pregnancy diabetes	Points
Prevalence of pre-pregnancy diabetes ≥75th percentile	1
Prevalence of pre-pregnancy diabetes <75th percentile	0

• *Pre-Pregnancy Hypertension*

One point will be awarded if the prevalence of pre-pregnancy

hypertension among women in the area is greater than or equal to the 75th percentile among all counties in the nation. If the prevalence of pre-

pregnancy hypertension among women in the area is less than the 75th percentile among all counties, zero points will be awarded.

Pre-pregnancy hypertension	Points
Prevalence of pre-pregnancy hypertension ≥75th percentile	1
Prevalence of pre-pregnancy hypertension <75th percentile	0

• *Prenatal Care Initiation in the 1st Trimester*

One point will be awarded if the prevalence of women who did not

initiate prenatal care in the first trimester of their pregnancy is greater than or equal to the 75th percentile among all counties in the nation. Zero points will be awarded if the prevalence

of women who did not initiate prenatal care in the first trimester of their pregnancy is less than the 75th percentile among all counties.

Prenatal care in first trimester	Points
Prevalence of No Prenatal Care in First Trimester ≥75th percentile	1
Prevalence of No Prenatal Care in First Trimester <75th percentile	0

¹¹ Robbins, Cheryl L., et al. “Preconception Health Indicators for Public Health Surveillance.”

Journal of Women’s Health, vol. 27, no. 4 (2018): 430–43.

¹² *Ibid.*

Diana Espinosa,
Acting Administrator.
[FR Doc. 2021–20855 Filed 9–24–21; 8:45 am]
BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statutory Requirements and Process Standardization: Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program Model Eligibility Review

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

ACTION: Request for public comment.

SUMMARY: HRSA, in partnership with the Administration for Children and Families (ACF) within HHS, oversees the MIECHV Program, which supports voluntary, evidence-based home visiting services during pregnancy and to families with young children up to kindergarten entry. HRSA proposes to standardize a process for also assessing Home Visiting Evidence of Effectiveness (HomVEE)-approved home visiting models against the MIECHV statutory requirements for a model to determine which of the HomVEE-approved models can be used to implement the MIECHV Program.

DATES: Comments on this request for public comment should be received no later than November 26, 2021.

ADDRESSES: Submit your comments to homevisiting@hrsa.gov with “MIECHV Model Eligibility” in the subject line.

SUPPLEMENTARY INFORMATION:

Invitation to comment: HRSA invites comments regarding this notice. To ensure that your comments are clearly stated, please identify the section of this notice that your comments address.

1.0 Background

The MIECHV Program provides voluntary, evidence-based home visiting services to pregnant people and families with young children up to kindergarten entry living in at-risk communities.¹ States, jurisdictions, certain non-profit organizations, and Tribal entities are eligible to receive funding from the MIECHV Program to implement service delivery model(s) that meet statutory requirements, including HHS criteria for evidence of effectiveness.^{2,3}

The MIECHV authorizing statute specifies that a model selected by an eligible entity must include certain key components, including that it “conform to a clear consistent home visitation model that has been in existence for at least 3 years and is research-based, grounded in relevant empirically-based knowledge, linked to program determined outcomes, associated with a national organization or institution of higher education that has comprehensive home visitation program standards that ensure high-quality service delivery and continuous program quality improvement.”⁴ In addition, the MIECHV-funded program must adhere to statutory standards applicable to model use, including adherence “to a clear, consistent model that satisfies the requirements of being grounded in empirically-based knowledge related to home visiting and linked to the benchmark areas specified in [statute] and the participant outcomes

described in [statute] related to the purposes of the program.”⁵ Home visiting programs could not achieve the standards described in the program’s authorizing statute without the support of home visiting models.

HRSA, in collaboration with ACF, has developed a proposed transparent and standardized process for assessing home visiting service delivery model(s) against statutory requirements to determine model eligibility for implementation through the MIECHV Program. Through this notice, HRSA seeks to provide public notice of the proposed process and gather public comment, including from stakeholders. Since the establishment of this process may affect critical decision-making, and to better understand the implications of these changes for various stakeholders, HRSA seeks public comment on the proposed process for assessing home visiting models against the MIECHV statutory requirements. HRSA will consider these comments in finalizing this process.

2.0 Process for Assessing Eligibility Against Statutory Requirements for a Home Visiting Model

This notice presents statutory requirements for a MIECHV service delivery model and the proposed process to assess home visiting models against each MIECHV statutory requirement. Then, the notice will present the proposed process, with timeline, for collecting information to assess whether the model(s) meet these requirements and therefore can be used to implement the MIECHV Program.

2.1 Model Eligibility Requirements

Requirement	Standard used	Statutory citation of requirement
REQUIREMENT (1): Model is appropriate for voluntary service provision.	There is evidence of model effectiveness in a voluntary setting.	Social Security Act, Title V, § 511(e)(7)(A).
REQUIREMENT (2): The model conforms to a clear consistent home visitation model.	The model conforms to HomVEE’s definition of an early childhood home visiting model.	Social Security Act, Title V, § 511(d)(3)(A)(i)(I).
REQUIREMENT (3): The model . . . has been in existence for at least 3 years.	The model is currently active and was first developed at least 3 years ago; OR The model is inactive and was first developed at least 3 years before a model developer stopped providing implementation support; OR The model was implemented as a demonstration project that lasted at least 3 years.	Social Security Act, Title V, § 511(d)(3)(A)(i)(I).

¹ The MIECHV Program is authorized by Social Security Act, Title V, § 511; Section 50601 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) (BBA) extended appropriated funding for the MIECHV Program through FY 2022.

² In current practice, HHS uses the HomVEE review to conduct a thorough and transparent review of the home visiting research literature and provide an assessment of the evidence of effectiveness for home visiting program models that

target families with pregnant people and children from birth to kindergarten. Information about the HomVEE review is at <https://homvee.acf.hhs.gov/>.

³ By law, state and jurisdictional awardees must spend the majority of their MIECHV Program grants to implement evidence-based home visiting models, with up to 25 percent of funding available to implement a model that conforms to a promising and new approach to achieving the benchmark areas specified in Social Security Act, Title V, § 511

(d)(1)(A) and the participant outcomes described in Social Security Act, Title V, § 511 (d)(2)(B), has been developed or identified by a national organization or institution of higher education, and will be evaluated through well-designed and rigorous process.

⁴ Social Security Act, Title V, § 511(d)(3)(A)(i)

⁵ Social Security Act, Title V, § 511(d)(3)(B)