Agency intends to address this authority in a separate guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Expedited Program for Serious Conditions—Accelerated Approval of Drugs and Biologics.'' 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.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This draft guidance contains proposed collections of information including information submitted to FDA in support of maintaining an accelerated approval. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to publish a 60-day notice in the **Federal Register** soliciting public comment on each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA will publish a 60-day notice on the proposed collections of information in this draft guidance in a separate issue of the **Federal Register**. This notice will encompass the collection of information discussed in the guidance relating to expedited procedures for the withdrawal of accelerated approval of drugs and biologics. Those procedures include the sponsor's submission of their objections to withdrawal as well as their supporting data and evidence. This collection of information is not included in any currently approved information collection.

This draft guidance also refers to previously approved FDA collections of information. The collections of information in 21 CFR parts 10, 12–16, and 19 pertaining to administrative practice and procedures have been approved under OMB control number 0910–0191. The collections of information in 21 CFR part 312 relating to clinical trials associated with accelerated approval pathways have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 relating to the submission of new drug applications, including accelerated approval of new drugs for serious or life-threatening conditions, have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 relating to the submission of biologics license applications have been approved under OMB control number 0910–0338. The collections of information pertaining to expedited programs for serious conditions for drugs and biologics and breakthrough therapy-designation for drugs and biologics have been approved under OMB control number 0910–0765.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: November 27, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–28392 Filed 12–5–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Public Comment Request: Request for Information Regarding HRSA Sickle Cell Disease Programs

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

ACTION: Notice of request for public comment.

SUMMARY: HRSA's Maternal and Child Health Bureau Sickle Cell Disease (SCD) Programs are requesting input from the public to inform future SCD program development.

DATES: Submit comments no later than January 6, 2025.

ADDRESSES: Submit electronic comments to *scdprograms@hrsa.gov.* Please submit your response only one time.

FOR FURTHER INFORMATION CONTACT: Oriana Sanchez, Public Health Analyst, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; *scdprograms@hrsa.gov* or call (347) 415–1458.

SUPPLEMENTARY INFORMATION: SCD is a group of inherited red blood cell disorders affecting an estimated 100,000 individuals in the United States. The Centers for Disease Control and Prevention report that SCD is a lifelong condition disproportionately affecting Black (1 of every 365 births) and Hispanic Americans (1 of every 16,300 births) with cases also occurring in individuals of Mediterranean, Middle Eastern, and Asian descent. SCD causes the body to produce red blood cells that are crescent shaped which impedes blood flow and cause anemia, severe pain, organ damage and other complications. Without access to comprehensive and routine services, life expectancy is greatly reduced for individuals with SCD. HRSA currently funds a portfolio of three coordinated programs with several recipients to improve outcomes of individuals with SCD and their families: the SCD Newborn Screening Follow-up Program (authorized by 42 U.S.C. 701(a)(2) (sec. 501(a)(2) of the Social Security Act)) funds 25 community-based organizations, the SCD Treatment Demonstration Program (authorized by 42 U.S.C. 300b–5(b) (sec. 1106(b) of the Public Health Service Act)) funds five regional organizations, and one Hemoglobinopathies National Coordinating Center (authorized by 42 U.S.C. 300b–5(b) (sec. 1106(b) of the Public Health Service Act).

Together the programs strengthen the SCD system of care and support by (1) educating patients, families, and clinicians to improve knowledge and capacities; (2) linking individuals and families to evidence-based care; and (3) fostering partnerships between clinicians, community organizations, and other stakeholders to improve the ability to deliver coordinated, comprehensive care across the lifespan. HRSA's SCD portfolio seeks to support and strengthen regional networks of SCD care, education, and social services across the United States. More information about the HRSA SCD programs is available online at: *https://mchb.hrsa.gov/programs-impact/programs/sickle-cell.*

Responses

HRSA is seeking responses that address the following questions. A response to each question is not required. When drafting responses, highlight strategies that HRSA should consider or prioritize to meet the needs of individuals with SCD and their families within the United States.

1. What are the best ways to improve the *quality of life* of individuals living with SCD?

2. What strategies or best practices are needed to ensure individuals with SCD receive *comprehensive evidence-based health care*? If possible, describe different strategies needed for children and for adults in both healthcare (*e.g.,* clinics, hospitals) and non-healthcare settings (*e.g.,* education, housing, transportation).

3. What are the barriers to ensuring infants identified with SCD through *newborn screening* are receiving appropriate follow-up care? What strategies or practices best address these barriers?

4. What are the barriers to successful *transition from pediatric to adult* serving systems? What strategies are available for individuals with SCD to receive evidence-based, comprehensive care as they transition into adulthood (*e.g.,* in clinics, hospitals)? What strategies or programs (*e.g.,* community health worker programs) have successfully transitioned individuals with SCD in non-health settings (*e.g.,* education, employment, and living situations)?

5. What are the challenges to improving the *systems of care* that support individuals with SCD and their families across the lifespan more broadly? Please share strategies that can bridge the gaps between systems that address healthcare (*e.g.,* clinics, hospitals) and systems that address social determinants of health (*e.g.,* education, housing, transportation)?

Respondents can also provide additional comments or recommendations that are not specifically linked to the questions above. All responses may, but are not required to, identify the individual's name, address, email, telephone number, professional or organizational affiliation, background or area of expertise (*e.g.,* program participant, family member, clinician, public health worker, researcher, HRSA SCD grantee), and topic/subject matter. Information obtained as a result of this request for information (RFI) may be used by HRSA for program planning. Comments in response to this RFI may be made publicly available, so respondents should bear this in mind when making comments. HRSA will not respond to any individual comments.

Special Note to Commenters

Whenever possible, respondents are asked to draw their responses from objective, empirical, and actionable evidence and to cite this evidence within their responses. The information obtained through this RFI may help inform the next iteration of the HRSA SCD portfolio of investments. This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal, applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or make a grant or cooperative agreement award. Further, HRSA is not seeking proposals through this RFI and will not accept unsolicited proposals. HRSA will not respond to questions about the policy issues raised in this RFI. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. Not responding to this RFI does not preclude participation in any future procurement or program, if conducted.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–28558 Filed 12–5–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Strategic Preparedness and Response

Request for Information on Hospital Preparedness Program Funding Formula

AGENCY: Administration for Strategic Preparedness and Response (ASPR), U.S. Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with section 319C–2 of the Public Health Service (PHS) Act, the Administration for Strategic Preparedness and Response (ASPR) distributes Hospital Preparedness Program (HPP) cooperative agreement funding to recipients using a statutorily required formula. ASPR is seeking comment on the risk component of the HPP funding formula to inform potential future changes to the formula.

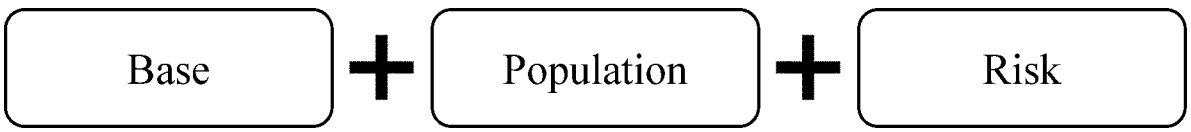
DATES: Comments on this notice must be received by December 20, 2024. ASPR will not reply individually to responders but will consider all comments submitted by the deadline.

ADDRESSES: Please submit all responses to the following email address: *HPP@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Jennifer Hannah, Director, Office of Health Care Readiness (OHCR) via *Jennifer.Hannah@hhs.gov* or call: 202–245–0722.

SUPPLEMENTARY INFORMATION: HPP is a cooperative agreement program that, through its support for health care coalitions, prepares the nation's health care delivery system to save lives during emergencies that exceed the day-to-day capacity of health care and emergency response systems. HPP is the primary source of federal funding for health care preparedness and response. HPP provides funding to 62 recipients, including the governments of all 50 states, eight U.S. territories and freely associated states, the District of Columbia, Chicago, New York City, and Los Angeles County. For the purposes of this Request for Information (RFI), ''the health care delivery system'' refers to all organizations and persons whose mission is to promote, restore, optimize, or maintain health.

Section 319C–2 of the PHS Act requires ASPR to distribute HPP funding based on the following factors: a required base amount determined by the HHS Secretary, a required adjustment based on population, and an amount based on significant unmet need and degree of risk.



The risk component accounts for health care risks and hazards capable of creating a surge for the U.S. health care delivery system. ASPR calculates the health care surge-specific risk component using publicly available national datasets to account for three subcomponents: