FOR FURTHER INFORMATION CONTACT: Paul Gouge, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 51, Rm. 6328, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3093, *paul.gouge@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft information sheet guidance for sponsors, clinical investigators, and IRBs entitled ''Frequently Asked Questions—Statement of Investigator (Form FDA 1572) (Revision 1).'' The draft guidance proposes to revise responses to the following questions from the Form FDA 1572 FAQ Guidance:

- Question 10: Must investigators who conduct studies outside the United States sign a 1572?
- Question 11: If a foreign clinical study is being conducted under an IND [investigational new drug application], what are the investigator's responsibilities with respect to regional, national, or local laws and regulations?
- Question 13: If a sponsor chooses to conduct a foreign clinical study under an IND and the investigators at the non-U.S. sites follow the recommendations in the [International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use] ICH E6 Good Clinical Practice Consolidated Guidance, would the non-U.S. investigators also be in compliance with FDA's IND requirements under 21 CFR part 312?

The above questions now include reference to the Form FDA 1572 waiver process. Further, the draft guidance proposes the addition of a new section describing the Agency's current thinking regarding the Form FDA 1572 signature waiver process. The new section is entitled ''Section #9: Form FDA 1572 Signature Waiver.'' This new section outlines the process for submitting requests to FDA for waivers from the Form FDA 1572 signature requirements when investigators cannot or will not sign the Form FDA 1572 for clinical studies conducted in foreign countries, and the sponsor wishes to conduct the study at the foreign sites under an IND. The new section also provides information regarding the documentation that may be included in the 1572 signature waiver request.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). Based on the comments received to the docket, we intend to revise the Form FDA 1572 FAQ Guidance to amend our responses to questions (such as general questions 10, 11, and 13) from that document and to include a new section (see questions 39 through 46 of the draft guidance) about waivers of the Form FDA 1572 signature requirement, the subjects addressed in this draft guidance. This draft guidance is not intended to be finalized as a separate guidance document but will be consolidated with the Form FDA 1572 Guidance and issued as one comprehensive guidance. When finalized, the consolidated guidance will represent the current thinking of FDA on ''Frequently Asked Questions—Statement of Investigator (Form FDA 1572) (Revision 1).'' 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

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: May 14, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–10612 Filed 5–19–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Medical Reserve Corps Request for Information

AGENCY: Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

ACTION: Request for information.

SUMMARY: The American Rescue Plan provides $100 million to the Medical Reserve Corps (MRC) program. To inform a strategic and impactful plan for execution of this funding, HHS is issuing this Request for Information (RFI). The RFI solicits specific input regarding current strengths and needs of MRC units and stakeholders, resource gaps highlighted during the COVID–19 response, and recommendations for short- and long-term priorities for the MRC. The set of questions is available in the **SUPPLEMENTARY INFORMATION** section below.

DATES: To be considered, public comments must be received electronically no later than midnight eastern standard time (EST) 30 days after posting.

ADDRESSES: Public comments should be submitted online at *http://www.regulations.gov.* All submissions must be submitted to the Docket named HHS–ASPR–2021–0013 to ''Request for Information (RFI) from Non-Federal Stakeholders: Advancing the Medical Reserve Corps with the American Rescue Plan.'' Comments submitted electronically, including attachments, will be posted to the docket unchanged and available to view by the public. Evidence and information supporting your comment can be submitted as attachments. Please provide your contact information or organization name on the web-based form for possible follow up from HHS. There is a 5,000 character limit on comments and maximum number (10) of attached files and maximum size (10 MB) of each attached file.

FOR FURTHER INFORMATION CONTACT: Esmeralda Pereira, MSPH, Director, Medical Reserve Corps Program, Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services, Washington, DC, (202) 205–0065 or *esmeralda.pereira@hhs.gov.*

SUPPLEMENTARY INFORMATION: The Volunteer Medical Reserve Corps is authorized by Section 2813 of the Public Health Service Act [42 U.S.C. 300hh–15]. The MRC program supports a national network of over 200,000

volunteers organized into approximately 760 local community-based units. MRC units are committed to improving local emergency response capabilities, reducing vulnerabilities, and building community preparedness and resilience. More than 500 MRC units in 48 states, the District of Columbia, Puerto Rico, American Samoa, and the Northern Mariana Islands have bolstered local emergency response capabilities and served as critical medical and public health response assets during the COVID–19 pandemic.

The American Rescue Plan provides an unprecedented opportunity to invest in and advance the Medical Reserve Corps. The RFI seeks public input on the current strengths and needs of MRC units and stakeholders, resource gaps highlighted during the COVID–19 response, and recommendations for short- and long-term priorities for the MRC. Responses may address one or more of the areas below:

1. What do you see as the top strengths of the Medical Reserve Corps? Has the COVID–19 pandemic highlighted new or different strengths of the MRC?

2. What do you see as the top needs or resource gaps of the MRC? Has the COVID–19 pandemic highlighted new or different needs of the MRC?

3. Do you have recommendations on the top short- and long-term priorities for the MRC? What operational capabilities, services, or competencies would you propose that the MRC focus on? Do you have recommendations on ways to strengthening the MRC's role as a federal disaster response asset?

4. Any additional topics you wish to provide input on.

The information received will inform the planning for executing the American Rescue Plan funding.

Nikki Bratcher-Bowman,

Acting Assistant Secretary for Preparedness and Response.

[FR Doc. 2021–10618 Filed 5–19–21; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Notice of Purchased/Referred Care Delivery Area Redesignation for the Northwestern Band of the Shoshone Nation

AGENCY: Indian Health Service, Department of Health and Human Services.

ACTION: Final notice.

SUMMARY: Notice is hereby given that the Indian Health Service has decided to expand the geographic boundaries of the Purchased/Referred Care (PRC) Delivery Area for the Northwestern Band of the Shoshone Nation (NWBSN) in the State of Utah to include the Utah counties of Davis, Salt Lake, and Weber. The final PRC delivery area for the NWBSN is Box Elder County, Davis, Salt Lake, and Weber counties in the State of Utah. The sole purpose of this expansion is to authorize NWBSN to cover additional Tribal members and beneficiaries to receive PRC services.

DATES: This expansion is applicable as of the publication date of this notice.

ADDRESSES: This notice can be found at *https://www.federalregister.gov.* Written requests for information should be delivered to: CAPT John Rael, Director, Office of Resource Access and Partnerships, Indian Health Service, 5600 Fishers Lane, Mail Stop 10E85C, Rockville, MD 20857, (301) 443–0609 (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: The IHS currently provides services under regulations in effect on September 15, 1987, and republished in the Code of Federal Regulations (CFR) at 42 CFR part 136, subparts A–C. Subpart C defines a Contract Health Service Delivery Area (CHSDA), now referred to as a Purchased/Referred Care delivery area (PRCDA), as the geographic area within which PRC will be made available by the IHS to members of an identified Indian community who reside in the area. Residence in a PRCDA by a person who is within the scope of the Indian health program, as set forth in 42 CFR 136.12, creates no legal entitlement to PRC but only potential eligibility for services. Services needed but not available at an IHS or Tribal facility are provided under the PRC program depending on the availability of funds, the relative medical priority of the services to be provided, and the actual availability and accessibility of alternate resources in accordance with the regulations.

As applicable to the Tribes, these regulations provide that, unless otherwise designated, a PRCDA shall consist of a county which includes all or part of a reservation and any county or counties which have a common boundary with the reservation (42 CFR 136.22(a)(6)). The regulations also provide that after consultation with the Tribal governing body or bodies on those reservations included within the PRCDA, the Secretary may from time to time, redesignate areas within the United States (U.S.) for inclusion in or exclusion from a PRCDA. The regulations require that certain criteria must be considered before any redesignation is made. The criteria areas follows:

(1) The number of Indians residing in the area proposed to be so included or excluded;

(2) Whether the Tribal governing body has determined that Indians residing in the area near the reservation are socially and economically affiliated with the Tribe;

(3) The geographic proximity to the reservation of the area whose inclusion or exclusion is being considered; and

(4) The level of funding which would be available for the provision of PRC, 42 CFR 136.22(b),

Additionally, the regulations require that any redesignation of a PRCDA must be made in accordance with the Administrative Procedures Act (5 U.S.C. 553). In compliance with this requirement, IHS published a proposed notice of redesignation and requested public comments on July 10, 2020 (85 FR 41597). No comments were received.

In support of this expansion, IHS adopts the following findings of the NWBSN, which had requested that IHS expand the NWBSN PRCDA to include Davis, Salt Lake, and Weber Counties in the State of Utah:

1. By expanding, the IHS estimates the current eligible population will be increased by 171.

2. The NWBSN has determined that these 171 individuals are members of the NWBSN and they are socially and economically affiliated with the NWBSN.

3. The expanded area including Davis, Salt Lake, and Weber Counties in the State of Utah maintain a boundary on or near the current Box Elder County, Utah PRCDA.

4. The NWBSN will use its existing Federal allocation for PRC funds to provide services to the expanded population. No additional financial resources will be allocated by IHS to the NWBSN to provide services to NWBSN members residing in Davis, Salt Lake, and Weber counties in the State of Utah.

Public Comments: IHS did not receive any public comments in response to the proposed notice of redesignation.