Dated: March 9, 2020.

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[FR Doc. 2020–05174 Filed 3–16–20; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 73

[Docket No. CDC–2020–0024]

RIN 0920–AA71

Possession, Use, and Transfer of Select Agents and Toxins; Biennial Review

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Advance notice of proposed rulemaking and request for comments.

SUMMARY: In accordance with section 351a of the Public Health Service Act, the Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS; hereafter referred to as HHS/CDC) has initiated a review of the HHS list of biological agents and toxins that have the potential to pose a severe threat to public health and safety (HHS select agents and toxins). This review was initiated within two years of the completion of the previous review. In reviewing the list, HHS/CDC is considering whether to propose amending the HHS list of select agents and toxins.

DATES: Comments should be received on or before May 18, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2020–0024 or Regulation Identifier Number (RIN) 0920–AA71, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21–7, Atlanta, Georgia 30329, ATTN: RIN 0920–AA71.

Instructions: All submissions received must include the agency name and RIN for this rulemaking. All relevant comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket Access: For access to the docket to read background documents or comments received, or to download an electronic version of the advance notice of proposed rulemaking, go to *http://www.regulations.gov.* Comments will be available for public inspection Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m. at 1600 Clifton Road NE, Atlanta, GA, 30329. Please call ahead to 1–866–694–4867 and ask for a representative in the Division of Select Agents and Toxins (DSAT) to schedule your visit. Please be aware that comments and other submissions from members of the public are made available for public viewing without changes.

FOR FURTHER INFORMATION CONTACT: Samuel S. Edwin Ph.D., Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21–7, Atlanta, Georgia 30329. Telephone: (404) 718–2000.

SUPPLEMENTARY INFORMATION: The preamble to this advance notice of proposed rulemaking is organized as follows:

I. Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. Comments are welcomed on any topic related to this advance notice of proposed rulemaking.

In addition, HHS/CDC invites comments specifically as to whether there are additional biological agents or toxins that should be added or removed from the HHS list of select agents and toxins based on the following criteria outlined under 42 U.S.C. 262a(a)(1)(B):

(1) ''The effect on human health of exposure to the agent or toxin''
(2) ''The degree of contagiousness of the agent or toxin and the methods by which the agent or toxin is transferred to humans''
(3) ''The availability and effectiveness of pharmacotherapies to treat or immunizations to prevent any illness resulting from infection by the agent or exposure to the toxin''
(4) ''Any other criteria including the needs of children and other vulnerable populations'' and any other criteria that the commenter believes should be considered.

Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Commenters should not include any information in their comments or supporting materials that they consider confidential or inappropriate for public disclosure. HHS/CDC will carefully consider all comments submitted.

II. Background

Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Response Act) (42 U.S.C. 262a(a)(1)), the HHS Secretary must establish by regulation a list of biological agents and toxins that have the potential to pose a severe threat to public health and safety. In determining whether to include a biological agent or toxin on the list, the Bioterrorism Response Act (42 U.S.C. 262a(a)(1)(B)) requires that the HHS Secretary consider the following criteria: The effect on human health of exposure to an agent or toxin; the degree of contagiousness of the agent and the methods by which the agent or toxin is transferred to humans; the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent illnesses resulting from an agent or toxin; and any other criteria including the needs of children and other vulnerable populations that the HHS Secretary deems relevant.

Under 42 U.S.C. 262a(a)(2), the HHS Secretary must review and republish the list of HHS select agents and toxins at least biennially. For this review, HHS/CDC evaluated as discussed below each agent and toxin based on: The degree of pathogenicity (ability of an organism to cause disease); dissemination efficacy; aerosol stability; matrix stability; ease of production; ability to genetically manipulate or alter; severity of illness; case fatality rate; long-term health effects; rate of transmission; available treatment; status of host immunity (*e.g.* whether an individual has already been

exposed to the agent and generated an immune response); vulnerability of special populations; decontamination and restoration (the extent remediation efforts are needed due to agent persistence in the environment and population); and the burden or impact on the health care system.

The results of the previous biennial review, discussed in a final rule published in the **Federal Register** on January 19, 2017 (82 FR 6278), were that HHS/CDC would make no changes to the list of HHS select agents and toxins at that time. Given that HHS/CDC is again considering whether to remove select agents and toxins as proposed in a previous notice of proposed rulemaking (81 FR 2805, January 19, 2016), HHS/CDC will consider the 35 public comments received from that notice as part of this biennial review. The current list of HHS select agents and toxins can be found at 42 CFR 73.3 (HHS select agents and toxins) and 42 CFR 73.4 (Overlap select agents and toxins), and is available at *https://www.selectagents.gov/SelectAgentsandToxinsList.html.*

As noted above, the list of HHS select agents and toxins is divided into two sections. The biological agents and toxins listed in 42 CFR 73.3 (HHS select agents and toxins) have the potential to pose a severe threat to human health and safety and are regulated only by HHS. The biological agents listed in § 73.4 (overlap select agents and toxins) have not only the potential to pose a severe threat to human health and safety; but have been determined by the USDA, pursuant to USDA's authority under the Agriculture Bioterrorism Protection Act of 2002 (7 U.S.C. 8401), to have the potential to pose a severe threat to animals and animal products. Accordingly, these biological agents are jointly regulated by HHS and USDA as ''overlap'' select agents. The Bioterrorism Response Act defines the term ''overlap agent or toxin'' to mean a biological agent or toxin that is listed pursuant to 42 U.S.C. 262a and is listed pursuant to 7 U.S.C. 8401. See 7 U.S.C. 8411. If HHS/CDC removes any overlap select agents from its list, these agents might still be regulated as USDA select agents dependent on the outcome of USDA biennial review.

III. Modifications to the List of Select Agents and Toxins Being Considered

The purpose of this advance notice of proposed rulemaking is to seek public comment on potential changes to the current list of HHS and overlap select agents and toxins. Specifically, we are providing an opportunity for interested persons to submit comments, including peer reviewed research data, that will better inform us as to whether there are: (1) Any biological agents or toxins that should be added to the select agents and toxin list because they have the potential to pose a severe threat to public health and safety; and (2) biological agents or toxins currently on the list that should be removed because they would no longer be considered to have the potential to pose a severe threat to public health and safety.

In addition, HHS/CDC is seeking comment on the following specific changes to the list of HHS and overlap select agents under consideration:

A. Select Agents and Toxins Under Consideration

i. Botulinum Neurotoxin Producing Species of *Clostridium*

Botulism is a serious paralytic disease caused by a neurotoxin produced during the growth of the spore-forming bacterium *Clostridium botulinum* (or rarely, *C. argentinense* (Puig de Centorbi et al., 1997), *C. butyricum,* or *C. baratii*) (Sobel, 2005). As such, the organism itself does not normally cause disease. HHS/CDC is seeking any information that will help inform our deliberations regarding if *Clostridium botulinum* should be treated consistently with the regulation of other select toxins in which a toxin is regulated but not the organism that produces the toxin. For example, *Staphylococcus aureus* is not listed as a select agent, yet Staphylococcal enterotoxins A,B,C,D,E subtypes are regulated toxins.

Should Botulinum neurotoxin producing species of *Clostridium* be removed or retained as an HHS select agent? Please provide a detailed explanation for your response.

ii. Coxiella burnetii

Q fever is a disease caused by the bacteria *Coxiella burnetii.* Q fever is an acute febrile disease that varies in severity and duration. Based on the criteria for listing select agents specified under 42 U.S.C. 262a(a)(1)(B), HHS/CDC is seeking comments from the public to provide any information not included below to help inform our deliberations regarding *C. burnetii:*

- Q fever has a low mortality rate (≤2%) with antibiotic treatment (Rolain et al., 2005). *C. burnetii* is susceptible to a number of readily available antibiotics including tetracycline or doxycycline (Rolain et al., 2005).
- Only 0.2–0.5% of the Q fever cases progress past the acute infection stage (Cutler, 2007).
- A whole-cell killed vaccine (Q-Vax) is licensed in Australia and has been used to vaccinate U.S. researchers who were at risk (Seqiris Pty Ltd PV, 2014).

Should *C. burnetii* be removed or retained as an HHS select agent? Please provide a detailed explanation for your response.

iii. Rickettsia prowazekii

Rickettsia prowazekii causes epidemic typhus, which is a louse-borne disease. In 2012, HHS/CDC decided to retain *R. prowazekii* based in part in anticipation of studies being conducted that would help HHS/CDC to better understand the potential risk of an intentional release of this organism. As of 2019, these studies had not been conducted. Based on the criteria for listing select agents specified under 42 U.S.C. 262a(a)(1)(B), HHS/CDC is seeking comments from the public to provide any information not included below to help inform our deliberations regarding *R. prowazekii:*

- Transmissibility from person-to-person is low because *R. prowazekii* is usually transmitted via blood, although it can be spread through inhalation of louse feces (ID_{50}), the concentration for human inhalation routes is unknown, but is estimated to be 10^3–10^6 organisms based on non-human primate and other animal studies (Eremeeva et al., 2005, Pike, 1976 and Walker, 2003, Reynolds et al., 2003 and International Cooperation in Animal Biologics, 2004).
- This agent is difficult to grow and purify in quantities that would make it a viable biological weapon (Woodman et al., 1977).
- *R. prowazekii* is susceptible to readily available antibiotics and can be treated with a single dose of doxycycline when symptoms are present (Raoult et al., 1991).
- When grown in a laboratory, it is difficult to maintain the stability of the organism and therefore it would be difficult to disseminate efficiently to cause mass exposure or disease that would have a significant public health impact (Bovarnick et al., 1950).

Should *R. prowazekii* be removed or retained as an HHS select agent? Please provide a detailed explanation for your response.

iv. Bacillus anthracis (Pasteur Strain)

Bacillus anthracis is the bacteria that causes anthrax, an acute disease in animals and humans. In order to cause the disease anthrax, *B. anthracis* requires two plasmids, pX01 and pX02, which carry toxin and capsule genes (Luna et al., 2006). *B. anthracis* (Pasteur strain) lacks the pX01 plasmid that is needed to cause the disease (Ivins et al., 1986). HHS/CDC excluded the *B. anthracis* (Sterne strain) in 2003 because the strain lacks the pX02

plasmid that encodes for the capsule. However, HHS/CDC has retained *B. anthracis* (Pasteur strain) to date because of a concern that someone working in a laboratory could combine the Pasteur strain with the Sterne strain to produce the wild type phenotype *B. anthracis de novo,* a select agent. Based on the criteria for listing select agents specified under 42 U.S.C. 262a(a)(1)(B), HHS/CDC is seeking comments from the public to provide any information to help inform our deliberations regarding if *B. anthracis* (Pasteur strain) should be removed or retained as an HHS select agent? Please provide a detailed explanation for your response.

v. Brucella abortus, Brucella melitensis, and Brucella suis

Based on the criteria for listing select agents specified under 42 U.S.C. 262a(a)(1)(B), HHS/CDC is seeking comments from the public to provide any information not included below to help inform our deliberations regarding *B. abortus, B. melitensis,* and *B. suis:*

- *Brucella* infections have a low case fatality rate, with an untreated fatality rate usually ranging from 1–2% of those identified with the infection (Spickler, 2018).
- Disease caused by these bacteria is treatable with antibiotics (Spickler, 2018).
- There is no indication that *Brucella* is transmitted between people by casual contact under ordinary condition. Humans are typically infected from exposure to animal reservoirs or animal products; transmission to humans from wildlife is a rare event unless an individual directly handles infected animals, such as in butchering meat (Godfroid et al., 2013).
- Brucellosis causes mild clinical symptoms (flu-like illness); incubation periods typically range from 1 to 4 weeks, but can extend to 6 months (Olsen et al., 2018).

Should *B. abortus, B. melitensis,* and *B. suis* be removed or retained as an HHS select agent? Please provide a detailed explanation for your response.

vi. Venezuelan Equine Encephalitis Virus (VEEV) 1AB and 1C

VEEV usually causes mild to severe influenza-like symptoms. Based on the criteria for listing select agents specified under 42 U.S.C. 262a(a)(1)(B), HHS/CDC is seeking comments from the public to provide any information not included below to help inform our deliberations regarding VEEV 1AB and 1C:

- Case fatality rate is less than 0.7%. Serosurvey data from the 1995 Venezuelan 1C outbreak indicated that, of 75,000 estimated human cases, one-third reported to a clinic or hospital, and 3,000 (4%) were hospitalized for neuroinvasive disease (sequelae), demonstrating that two-thirds of the cases [in the 1995 outbreak] were mild or asymptomatic (Rivas et al., 1997).
- While it is theoretically possible for VEEV to be spread between humans since the virus is found in the pharynx of 6 to 40% of acutely ill patients, there is no documented evidence of human-to-human transmission (Smith et al., 2009).
- An effective equine vaccine is available and a range of humanized monoclonal antibodies are currently available for emergency use (Weaver et al., 1996). Restricted animal movement, insecticide application, and equine vaccinations are a part of effective control measures to contain VEE outbreaks and mitigate the spread of disease from equine to humans.

Should VEEV 1AB and 1C be removed or retained as an HHS select agent? Please provide a detailed explanation for your response.

vii. Short, Paralytic Alpha Conotoxins

Predatory cone snails (genus *Conus*) produce a rich array of venoms (conotoxins) that collectively contain an estimated 100,000 small, disulfide-rich peptides neurotoxins (Bulaj, 2008). Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$ are a group of neurotoxic peptides isolated from the venom of the marine cone snail, genus *Conus.* Based on the criteria for listing select agents specified under 42 U.S.C. 262a(a)(1)(B), HHS/CDC is seeking comments from the public to provide any information not included below to help inform our deliberations regarding short, paralytic alpha conotoxins:

- Production of pure preparations (chemical synthesis of larger quantities of appropriately folded peptides) is a challenge due to the thermodynamic instability of many conotoxins (Purcell et al., 2012) and most alpha-conotoxins harvested from the venom bulbs of cone snails are inactive precursors that are not in the functional form of the select toxin. To generate the functional form, soluble peptides of the appropriate amino acid sequence must be treated with proteases to properly fold and activate the toxin, which requires higher-level technical expertise and is a slow process involving several months (Wu et al., 2013).
- The optimal route of exposure for toxicity for conotoxins is through injection. However, even though there is currently no published literature to support conotoxins being administered via the inhalation route to achieve a toxic effect, the LD_{50} (dose required to kill half the members of a tested population after a specified test duration) is estimated at 20 µg/kg by inhalation (Thapa et al., 2014).

Should conotoxins (short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$) be removed or retained as a select toxin? If retained, should the exclusion amount for conotoxins be increased or decreased? Please provide a detailed explanation for your response.

viii. Diacetoxyscirpenol (DAS)

DAS, a derivative of tetracyclic sesquiterpenes called trichothecenes, is produced from strains of *Fusarium sambucinum* and related species that grow on barley, corn, oats, rye, or wheat. In 2005, HHS/CDC retained DAS because of limited understanding of the risk at the time of whether DAS has the potential to pose a severe threat to public health. The estimated LD_{50} of DAS for rodents is 2 to 16 mg/kg (Knutsen, H.K., et al., 2018).

Based on the criteria for listing select agents specified under 42 U.S.C. 262a(a)(1)(B), HHS/CDC is seeking comments from the public to provide any information to help inform our deliberations regarding DAS. Should DAS be removed or retained as a select toxin? If retained, should the DAS exclusion amount be increased or decreased? Please provide a detailed explanation for your response.

ix. Staphylococcal Enterotoxins

Staphylococcus aureus produces a number of exotoxins, one of which is Staphylococcal enterotoxin B, or SEB. SEB normally exerts its effect on the intestines and therefore is referred to as an enterotoxin. SEB is one of the pyrogenic toxins (causing fever) that commonly causes food poisoning in humans after the toxin is produced in improperly handled foodstuffs and subsequently ingested. Based on the criteria for listing select agents specified under 42 U.S.C. 262a(a)(1)(B), HHS/CDC is seeking comments from the public to provide any information not included below to help inform our deliberations regarding Staphylococcal enterotoxins:

- The estimated annual number of domestically acquired foodborne hospitalization (6% hospitalization rate) and deaths (<0.1% death rate) caused by *S. aureus* is low. (Scallan et al., 2011).
- The ED_{50} (concentration of a drug that produces a biological response) for Staphylococcal enterotoxins:
  - *Intravenously:* ED_{50} 0.03 µg/kg (rhesus monkeys) (Bergdoll, 1979)

○ *Ingestion:* ED_{50} 1 μg/kg (rhesus monkeys) (Bergdoll, 1979)

○ *Intragastrically:* ED_{50} 1.7 μg/kg (5 ug/monkey for 3 kg rhesus monkeys) (Donnelly et al., 1967)

Should Staphylococcal enterotoxins be removed or retained as a select toxin? If retained, should the Staphylococcal enterotoxins exclusion amount be increased or decreased? Please provide a detailed explanation for your response.

B. Biological Agents Under Consideration for Being Added to the HHS Select Agent and Toxin List

i. New World Hantaviruses

Some New World Hantaviruses can cause Hantavirus Pulmonary Syndrome (HPS) in humans. HPS is an acute febrile illness with a symptoms consisting of fever, chills, myalgia, headache, and gastrointestinal symptoms (Hooper et al., 2013). Based on the results of the ISATTAC evaluation of New World Hantaviruses, HHS/CDC is considering the addition of Sin Nombre virus (SNV) and Andes virus to the list of select agents because:

- The average case fatality rate in the United States from 1993 to 2016 is 36% (Centers for Disease Control and Prevention, 2017).
- Andes virus is capable of person-to-person transmission (Martinez et al., 2005 and Vitek et al., 1996).
- The infectious and lethal doses are very low. For Andes virus in hamsters, the infectious dose is estimated to be between 1–10 virus particles, and the lethal dose is estimated to be between 10–100 virus particles (Hooper et al., 2001 and Hooper et al., 2008).
- There are no FDA-approved vaccines or drugs to prevent or treat infection with Andes or SNV. Supportive care is the only current method of treatment for patients with HPS (Avsic-Zupanc et al., 2019).

Should Sin Nombre virus and Andes virus be added to the select agent list? Should other New World Hantaviruses be regulated as HHS select agents? In addition, HHS/CDC is seeking comments regarding the potential burden and time needed for an entity possessing SNV or Andes virus to come into compliance with the select agents and toxins regulatory requirements. Please provide a detailed explanation for your response.

ii. Old World Hantaviruses

Some highly pathogenic Old World Hantaviruses can cause severe Hemorrhagic Fever with Renal Syndrome (HFRS). HFRS is a generalized infection, and the severity of the disease as well as clinical patterns can manifest as mild, moderate or severe disease, depending upon the causative virus. HFRS caused by Hantaan and Dobrava viruses is more severe, while HFRS caused by Seoul virus is more moderate and by Puumala virus is mild (Jonsson et al., 2010). The clinical picture for Dobrava virus is severe with more hemorrhagic complications, shock (21 to 28%), oliguric renal failure (30 to 47%), and abdominal and pleural effusions (Maes et al., 2009). Due to the severity of disease with Hantaan virus and Dobrava virus, HHS/CDC is considering the addition of Hantaan virus and Dobrava virus to the list of select agents because:

- HFRS caused by Hantaan and Dobrava viruses are more severe than infection caused by other Old World Hantaviruses such as Seoul, Puumala, Sangassou, and Saaremma viruses (Maes et al., 2009 and Avsic-Zupanc et al., 2019).
- For Hantaan viruses, inhalation infectious dose (ID_{50}), is very low and in rats was 0.3–0.7 plaque-forming unit (Nuzum et al., 1988).

Should Hantaan virus and Dobrava virus be added to the select agent list? Should other Old World Hantaviruses be regulated as select agents? In addition, HHS/CDC is seeking comments regarding the potential burden and time needed for an entity possessing the Hantaan or Dobrava virus to come into compliance with the select agents and toxins regulatory requirements. Please provide a detailed explanation for your response.

C. Exclusion Limits Being Considered for the Following Toxins

Based on the criteria for listing select toxins specified under 42 U.S.C. 262a(a)(1)(B), HHS/CDC is seeking comments from the public to provide any information that will help inform our deliberations regarding this biennial review including increasing or decreasing the exclusion limit for the following toxins:

- Saxitoxin based on the LD_{50} by ingestion is estimated as 0.3–1.0 mg/person (Burrows et al., 1999) and estimated mortality rate of 15% for Paralytic Shellfish Poisoning (Rodrique, et al., 1990 and Hallegraeff, et al. 1995)
- Tetrodotoxin based on LD_{50} estimated 15–60 μg/kg by ingestion (Burrows et al., 1999); 2 μg/kg by inhalation; 8–14 μg/kg by injection (mouse, dog, rabbit) (Bane et al., 2014) and the recent puffer fish poisoning in 2008 Bangladesh involved 141 cases with 17 deaths (Islam et al., 2011)
- Botulinum neurotoxin estimated at 1 ug/kg by ingestion; 0.01–0.012 ug/kg by inhalation; 0.0013–0.0024 ug/kg by injection (Guzman et al., 2001)

D. Designating Nipah Virus as a Tier 1 Select Agent

Executive Order 13546 ''Optimizing the Security of Biological Select Agents and Toxins in the United States'' directed the HHS Secretary to designate a subset of the select agents and toxins list that present the greatest risk of deliberate misuse with the most significant potential for mass casualties or devastating effects to the economy, critical infrastructure, or public confidence. This subset of select agents and toxins is identified as Tier 1. HHS/CDC is seeking public comment on whether Nipah virus should be identified as a Tier 1 select agent. HHS/CDC is considering whether the Nipah virus should be designated as a Tier 1 agent because the public health threat posed by Nipah virus is similar to that of Marburg and Ebola viruses which are both currently Tier 1, with characteristics such as:

- Human transmissibility (person-to-person transmission has occurred) (Centers for Disease Control and Prevention, 2014; Gurley et al., 2007; Luby et al., 2012; and Luby et al., 2009).
- High case fatality rate (estimated between 40–100%) (World Health Organization, 2017 and Harcourt et al., 2004).
- Low infectious dose (ranging from 100–10^7 plaque forming units depending on route of infection) (DeWit et al., 2014; Geisbert et al., 2010; and Mathieu et al., 2012).
- High severity of illness (fever, headache, dizziness, vomiting, cough, reduced levels of consciousness, respiratory distress, and death) (Hoh et al., 2000; Hossain et al., 2008; and Lo et al., 2008).
- Severe long-term effects (neurological sequelae including encephalopathy, cranial nerve palsies, and dystonia) (Sejvar et al., 2007 and Lo et al., 2008). For entities that are currently registered to possess Nipah virus, they are also in possession of other Tier 1 select agents. Therefore, designating Nipah virus as Tier 1 select agent would not require an entity to meet additional requirements associated with Tier 1 agents. Should Nipah virus be identified as a Tier 1 select agent? Please provide a detailed explanation for your response.

V. References

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Dated: February 21, 2020.

Alex M. Azar II,

Secretary.

[FR Doc. 2020–05477 Filed 3–16–20; 8:45 am]

BILLING CODE 4163–18–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1 and 54

[AU Docket No. 20–34; WC Docket Nos. 10–90, 19–126; FCC 20–21; FRS 16543]

Comment Sought on Competitive Bidding Procedures and Certain Program Requirements for the Rural Digital Opportunity Fund Auction (Auction 904)

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; proposed auction procedures.

SUMMARY: In this document, the Federal Communications Commission (Commission) proposes and seeks comment on the procedures to be used for Phase I of the Rural Digital Opportunity Fund auction, designated as Auction 904.

DATES: Comments are due on or before March 27, 2020, and reply comments are due on or before April 10, 2020.

ADDRESSES: Comments may be filed using the Commission's Electronic Comment Filing System (ECFS) or by filing paper copies. *Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121 (May 1, 1998). All filings in response to the *Auction 904 Comment Public Notice* must refer to AU Docket No. 20–34; WC Docket No. 19–126; and WC Docket No. 10–90. The Commission strongly encourages interested parties to file comments electronically.

- *Electronic Filers:* Comments may be filed electronically using the internet by accessing the ECFS: *https://www.fcc.gov/ecfs/.* Filers should follow the instructions provided on the website for submitting comments. In completing the transmittal screen, filers should include their full name, U.S. Postal Service mailing address, and the applicable docket numbers, AU Docket No. 20–34; WC Docket No. 19–126; WC Docket No. 10–90.
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St. SW, Room TW–A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of before entering the building.

Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.

U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: For further information regarding this proceeding, contact Mark Montano in the Auctions Division of the Office of Economics and Analytics at (202) 418–0660 or Heidi Lankau in the Telecommunications Access and Policy Division, Wireline Competition Bureau, (202) 418–7400.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's document (*Auction 904 Comment Public Notice*), AU Docket No. 20–34; WC Docket Nos. 19–126 and 10–90; FCC 20–21, adopted on February 28, 2020 and released on March 2, 2020. The complete text of this document is available for public inspection and copying from 8:00 a.m. to 4:30 p.m. Eastern Time (ET) Monday through Thursday or from 8:00 a.m. to 11:30 a.m. ET on Fridays in the FCC Reference Information Center, 445 12th Street SW, Room CY–A257, Washington, DC 20554. The complete text is also available on the Commission's website at *http://www.fcc.gov/auction/904/* or by using the search function for AU Docket No. 20–34, WC Docket 19–126, or WC Docket 10–90 on the Commission's ECFS web page at *www.fcc.gov/ecfs/.* Alternative formats are available to persons with disabilities by sending an email to *FCC504@fcc.gov* or by calling the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY). Pursuant to sections 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated in the *Auction 904 Comment Public Notice* in AU Docket No. 20–34; WC Docket 19–126; and WC Docket 10–90.

I. Introduction

1. By the *Auction 904 Comment Public Notice,* the Commission initiates the pre-auction process for Phase I of the Rural Digital Opportunity Fund auction (auction or Auction 904). The auction will award up to $16 billion over 10 years to service providers that commit to offer voice and broadband services to fixed locations in eligible unserved high-cost census blocks. Bidding is expected to begin on October 22, 2020.

2. Auction 904 will be the Commission's second auction to award ongoing high-cost universal service support through competitive bidding in a multiple-round, reverse auction and follows the successful Connect America Fund (CAF) Phase II auction (Auction 903) that was completed in 2018. As with the CAF Phase II auction, the Commission intends to maximize the value the American people receive for the universal service dollars the Commission spends, balancing the need for future-proofed networks and higher-quality services against cost efficiencies. Therefore, the Commission will again use an auction mechanism designed to select bids from providers that would deploy high-speed broadband and voice services in unserved communities for lower relative levels of support.

3. The pre-auction and bidding procedures and processes proposed for this auction are similar to those that proved effective in the CAF Phase II auction. The Commission is proposing some new pre-auction and bidding procedures and processes that would be expected to materially improve upon the Auction 904 based upon its experience with Auction 903.

4. The Commission proposes and seeks comment in this Public Notice on the procedures to be used in Auction 904, including (i) how an applicant can become qualified to participate in the auction, (ii) how bidders will submit bids, and (iii) how bids will be processed to determine winners and assign support amounts. The Commission also seeks comment on,