SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* October 26, 2022.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on October 20, 2022, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service, and Parcel Select Service Contract 72 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–23, CP2023–22.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2022–23319 Filed 10–25–22; 8:45 am]

BILLING CODE 7710–12–P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Request for Information; Clinical Research Infrastructure and Emergency Clinical Trials

AGENCY: Office of Science and Technology Policy (OSTP).

ACTION: Notice of Request for Information (RFI) on clinical research infrastructure and emergency clinical trials.

SUMMARY: In accordance with the 2022 National Biodefense Strategy for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security (National Biodefense Strategy) and the American Pandemic Preparedness Plan (AP3), the White House Office of Science and Technology Policy (OSTP), in partnership with the National Security Council (NSC), is leading efforts to ensure that coordinated and large-scale clinical trials can be efficiently carried out across a range of institutions and sites to address outbreaks of disease and other emergencies. Efforts in this area could include the establishment of a U.S.-level governance structure and outreach to a wide range of institutions, clinical trial networks, and other potential trial sites that can participate in emergency research, both domestically and internationally. A further goal of this emergency clinical trials initiative is to support the expansion of clinical research into underserved communities, and increase diversity among both trial participants and clinical trial investigators. Building U.S. capacity to carry out emergency clinical trials will enlarge and strengthen the U.S. clinical trials infrastructure overall.

DATES: Interested persons and organizations are invited to submit comments on or before 5 p.m. ET on December 27, 2022.

ADDRESSES: Interested individuals and organizations should submit comments electronically to *emergencyclinicaltrials@ostp.eop.gov* and include ''Emergency Clinical Trials RFI'' in the subject line of the email. Due to time constraints, mailed paper submissions will not be accepted, and electronic submissions received after the deadline cannot be ensured to be incorporated or taken into consideration.

Instructions

Response to this RFI is voluntary. Each responding entity (individual or organization) is requested to submit only one response. Please feel free to respond to one or as many prompts as you choose.

Please be concise with your submissions, which must not exceed 8 pages in 12-point or larger font, with a page number on each page. Responses should include the name of the person(s) or organization(s) filing the comment.

OSTP invites input from all stakeholders, including members of the public, representing all backgrounds and perspectives. In particular, OSTP is interested in input from research institutions, clinical trialists, health care providers interested in clinical research, contract research organizations (CROs) and other clinical trial service providers, pharmaceutical and biotechnology companies, and community health care organizations. *Please indicate which of these stakeholder types, or what other description, best fits you as a respondent.* If a comment is submitted on behalf of an organization, the individual respondent's role in the organization may also be provided on a voluntary basis.

Comments containing references, studies, research, and other empirical data that are not widely published should include copies or electronic links of the referenced materials. No business proprietary information, copyrighted information, or personally identifiable information should be submitted in response to this RFI. Please be aware that comments submitted in response to this RFI may be posted on OSTP's website or otherwise released publicly.

In accordance with FAR 15.202(3), responses to this notice are not offers and cannot be accepted by the Federal Government to form a binding contract. Additionally, those submitting responses are solely responsible for all expenses associated with response preparation.

FOR FURTHER INFORMATION CONTACT: For additional information, please direct questions to Grail Sipes at 202–456–4444 or *emergencyclinicaltrials@ostp.eop.gov.*

SUPPLEMENTARY INFORMATION:

Background: Currently, the U.S. clinical trials infrastructure is not well prepared to carry out coordinated, large-scale clinical research in the event of an outbreak of infectious disease or other public health emergency. As was seen in the initial stages of the COVID–19 outbreak, different institutions and networks tend to implement their own research protocols and capture and store their own data. The lack of a coordinated approach to clinical trials research in emergency settings has slowed the development of actionable information, which has in turn delayed the availability of vaccines, therapeutics, and diagnostics; and may also impede the tracking of the outbreaks themselves. Without some mechanism to coordinate and organize research on a larger scale in an emergency setting, researchers and decisionmakers are left with a series of relatively small, often inconclusive studies, and assembling data for larger-scale analysis is challenging. In addition, and very significantly, our current approach to clinical research in the emergency setting excludes many patients and health care providers in underserved areas, and has contributed to a lack of diversity among clinical trial participants and among the investigators who lead clinical trials.

The National Biodefense Strategy calls for the U.S. government to maintain and build upon the domestic clinical trials infrastructure, with the addition of international sites as appropriate, to ensure readiness to ''expedite the evaluation of safe and effective vaccines, therapeutics, and diagnostics for all segments of the population during a nationally or internationally significant biological incident.'' [1] In addition, establishing an

[1] 2022 National Biodefense Strategy for Countering Biological Threats, Enhancing Pandemic

Continued

emergency clinical trials governance structure, developing the terms of an Emergency Master Agreement to accelerate response, and identifying a network of available sites are among the key goals towards implementation of AP3.[2] In line with these provisions, OSTP (in partnership with the NSC and other EOP components) is leading an effort to ensure that the U.S. can carry out more coordinated and potentially larger-scale clinical trials in emergency situations. These emergency situations could include emerging outbreaks with epidemic or pandemic potential, even in advance of any declaration of a public health emergency (PHE) under section 319 of the Public Health Services Act. By strengthening U.S. capacity to address such outbreaks and other biological incidents, OSTP's emergency clinical trials effort also aims to build and enhance U.S. clinical research capacity overall.

We seek comment below on potential governance models for the emergency clinical trials effort. One possible approach would include a centralized U.S.-level structure drawing membership from Federal agencies with relevant expertise. Governance functions might include determining when coordinated and potentially large-scale clinical research is needed, including research on countermeasures, to address outbreaks of disease or other biological incidents. As noted above, research on an outbreak or incident may sometimes be needed in advance of any section 319 PHE declaration; we solicit comments below on the criteria that should be applied to determine when emergency clinical research may be needed, and how that determination might be communicated to institutions and clinical trial networks that can participate in carrying out the research.

Another governance function might be to oversee the development of emergency clinical trial protocols, in coordination with stakeholders external to the U.S. government. The trials and other studies needed in emergency settings could vary in complexity. Some might be relatively simple studies designed to measure the scope of an outbreak or the course of a disease, in which the data captured from patients might overlap to a large extent with the data that would be gathered in the course of treatment. Other studies, including those designed to evaluate the efficacy and safety of investigational vaccines, therapeutics or diagnostics, would be more complex and could require more or different data elements from those that would be captured in the course of standard medical treatment. In some cases, study designs used in connection with prior outbreaks could provide useful models for developing protocols to address a new emergency. We request comment below on how a governing entity could best work with stakeholders to develop emergency clinical trial protocols.

We also seek comment below on how emergency clinical trial data should be managed to facilitate researchers' access to data and the analysis of results across a range of participating sites. One potential model would be to collect data from emergency clinical trials in a centralized data repository or small set of repositories, with a central biorepository for biospecimens collected during trials.

In order to ensure that coordinated, large-scale clinical trials can be carried out in the event of an emergency, OSTP seeks comment on how best to identify institutions and networks that have an interest in participating in these studies, and how to create or enhance incentives for them to participate wherever possible. In particular, OSTP seeks comment on how to ensure that trial sites in underserved areas are included, and how to increase diversity both among study participants and among the investigators who lead trials to completion. We also solicit feedback below on how to identify an adequate number and distribution of clinical trial sites, including trial sites located outside of the U.S. This could include sites that may currently be affiliated with a U.S.-based trial network, as well as other international sites. We would appreciate receiving comments on how the domestic emergency clinical trials effort overall can be designed to coordinate with international research and preparedness initiatives.

We are aware that in advance of an outbreak or other emergency, there may be value in having networks and sites begin carrying out clinical trials to create a ''warm base'' of clinical research capacity. ''Warm base'' is a term used to refer to studies that not only gather data under a particular clinical research protocol, but also serve the function of keeping trial sites in a state of readiness to undertake additional or future research. ''Warm base'' studies could address infectious diseases such as influenza, or other medical conditions that are of interest to researchers and communities, such as cancer and heart disease.

To participate in a clinical trial, a site needs to have staff familiar with applicable regulatory requirements and with the appropriate procedures for collecting data and submitting it to a study sponsor. When ''warm base'' research is initiated, site staff have an opportunity to gain familiarity with these procedures. ''Warm base'' research is a way to expand the number of sites that are able to participate in clinical trial research, which builds U.S. clinical trial capacity overall while enlarging the network of sites that can be available to carry out emergency clinical trial research when the need arises. We request comment below on a variety of issues related to ''warm base'' research, including disease areas that might be targeted and how ''warm base'' research can be implemented to provide targeted training for trial sites, as appropriate to staff roles. Given OSTP's goals of increasing diversity among clinical trial participants and among investigators, and of increasing capacity for clinical research in underserved areas, we are particularly interested in how those goals might be served through the implementation of ''warm base'' research.

In recent emergency settings, we have seen that the launch of clinical trials across separate institutions or networks can be delayed by the process of coming to agreement on certain key issues, such as data sharing and the publication of results. We seek comment below on the possibility of developing a framework of key terms that can be developed in advance of an emergency and integrated into clinical trial agreements for emergency clinical trials when needed. For purposes of this RFI, we refer to such a framework as an ''Emergency Master Agreement.'' The goal of an Emergency Master Agreement would be to shorten the time it takes to get emergency clinical trial research started across a range of sites, by facilitating agreement on key terms in advance. Certain basic terms could be relevant for any coordinated or large-scale emergency clinical trial, such as provisions that allow data gathered under common protocols from a range of sites to be collected and made readily accessible to researchers beyond the institutions where the trial was conducted. Other basic terms might include central management of biospecimens and the use of a single Institutional Review Board (IRB). In addition to these basic, core terms, an Emergency Master Agreement could include additional terms that might only be needed for certain types of study protocols (*e.g.,* if an investigational

Preparedness, and Achieving Global Health Security (October 2022), section 4.1.4.

[2] First Annual Report on Progress Towards Implementation of the American Pandemic Preparedness Plan (September 2022), at 22–23.

agent is being tested). We solicit input below on a range of issues related to the potential creation of an Emergency Master Agreement.

From a technical perspective, OSTP is also seeking input on how best to operationalize both protocol distribution and data capture in a forthcoming RFI.

Information Requested: Respondents may provide information for one or as many topics below as they choose.

1. Governance for emergency clinical trials response.

a. Descriptions of models that could be used to establish a U.S.-level governance structure for emergency clinical trials. As noted above, one possible approach would be a centralized U.S.-level structure drawing membership from Federal agencies with relevant expertise.

b. Criteria that should be applied in determining when coordinated and potentially large-scale clinical research is needed to address an outbreak of disease or other biological incident, including signals or indicators that should be taken into account.

c. Once a need for emergency clinical research is determined, factors relating to the outbreak or incident (*e.g.,* scope, location, severity) that should be considered in determining what types of studies are needed.

d. Methods for communicating the decision to begin emergency clinical research to institutions and clinical trial networks that can participate in carrying out the research.

e. Mechanisms for tracking institutions, networks and sites that might be able to participate in emergency research, to ensure adequate potential for enrollment and adequate geographic coverage, domestically and internationally.

i. Criteria for establishing a target number and location of sites needed to support clinical trials in case of emergency.

f. Procedures whereby the U.S. Government, together with external stakeholders, could oversee the development of clinical trial protocols and, where appropriate, the selection of investigational agents. It would be particularly helpful to get input on whether there is a role for public-private partnerships in this context.

g. Best practices, including ''quality by design'' principles, for designing trials so that they capture the data needed without unnecessary complexity that can complicate execution.

h. Best practices for designing trials that can enroll vulnerable populations, such as the pediatric population, as needed in particular circumstances.

i. Optimal ways to manage interactions with domestic and international regulatory bodies.

j. Appropriate entities to handle projecting and tracking enrollment at study sites, monitoring the progress of clinical trials, and data management; whether existing entities could be engaged or adapted to carry out these functions for coordinated, large-scale emergency clinical trials.

k. Appropriate ways to structure a data repository and a biorepository for emergency clinical trial data and specimens. As noted above, one potential model would be to collect data and biospecimens in centralized repositories. We would also appreciate input on whether existing entities could be engaged or adapted to handle these repository functions.

l. Criteria that should be applied to govern researchers' access to emergency clinical trial research data.

2. Identifying and Incentivizing Research Institutions and Networks; Building Diversity and Equity.

a. Methods for identifying institutions and sites that may have an existing interest in or familiarity with emergency clinical trial research. This might include those that currently receive government funding, those with a focus on infectious disease research, and/or those that have worked with CROs.

b. Effective ways to increase diversity among study participants and investigators, and to expand clinical research sites into underserved areas. It would be helpful to get input on whether and how the following approaches could be useful:

i. Community outreach.

ii. Use of decentralized clinical trial (DCT) design elements, or other innovative approaches such as trials conducted at the point of care.

iii. Use of technological innovations, such as digital health technologies (DHTs), that would allow remote participation or otherwise limit the need for participants to travel.

iv. Building on existing programs that target diversity in clinical research, including initiatives within research institutions and public-private collaborations.

v. Leveraging the networks and community access of retail chains, including retail pharmacy chains.

vi. Leveraging community-based care networks such as Practice-Based Research Networks (PBRNs) and Federally Qualified Health Centers (FQHCs).

c. Incentives that can be identified or enhanced to encourage participation in emergency clinical trial research.

i. As described above and in the forthcoming RFI on data capture for Emergency Clinical Trials and Data Collection Pilot, we are seeking information on how to create a pilot program enabling clinical trial data collection across a wide variety of trial sites that is easy for health care providers to use and can be scaled up for use in emergency research settings. It would be helpful to receive comments on whether the opportunity to participate in such a pilot could create an incentive for institutions and sites to participate in emergency clinical research studies.

d. Once interested institutions or networks are identified,

i. Effective ways to recognize and communicate their commitment to emergency clinical research to the health care community and to the public.

ii. Information that should be collected from interested sites, for example by means of a short questionnaire to assess characteristics of patient population, level of training that would be required, etc.

e. The best ways to provide training in clinical trial practice (including regulatory requirements such as Good Clinical Practice (GCP)) where needed, targeted as appropriate to staffs' roles, including staff at sites that may not have participated in clinical trials previously.

3. ''Warm Base'' Research.

a. Disease areas that should be targeted in protocols for ''warm base'' clinical research. It would be helpful to get comments on:

i. Disease areas that are most relevant to communities, including underserved communities and those that may have little experience with participating in clinical research.

ii. The extent to which ''warm base'' research should target infectious disease, versus other conditions such as cancer, heart disease, or rare disease; and the size or scope of site networks that would be needed to study various conditions.

b. How ''warm base'' research could best be implemented to provide training to sites that are inexperienced with clinical trial research, and to create a basic level of surge capacity at the staff level for emergency clinical trial research. We would appreciate input on other training mechanisms that could be used as well.

c. Whether ''warm base'' research could be appropriately supported as

i. A demonstration project with commercial partnership.

ii. A public-private partnership.

iii. An agency-funded program.

4. Emergency Master Agreement.

a. Basic terms that might form part of an Emergency Master Agreement, including the following.

i. *Data collection and use,* including ownership of the study data and biospecimens; entities that have the right to collect, store, and use the data and specimens; banking of biospecimens for further research.

ii. *Publication/accessibility of trial data,* including availability of data prior to publication and publication rights.

iii. *Use of a single IRB* across all participating trial sites. As a related point, it would be helpful to get feedback on whether an IRB should be established that is primarily devoted to emergency clinical trials.

b. Additional terms for an Emergency Master Agreement that could be added or modified depending on the complexity of the protocol, and on other factors such as whether a private sector sponsor or an investigational agent is involved. It would be helpful to have input on terms such as the following:

i. Confidentiality.

ii. Patents/intellectual property.

iii. Control of study drug.

iv. Indemnification.

v. Compensation for injury.

c. The best ways to get the input of research institutions, clinical researchers, community groups, and other key stakeholders on the content of Emergency Master Agreement terms.

d. Approaches to facilitating stakeholders' understanding and adoption of the Emergency Master Agreement framework.

i. Any models for such adoption in related areas, such as the NCATS SMART IRB Platform.

5. Identifying viable technical strategies for data capture; gathering information about a potential data capture pilot. This topic will be the subject of a separate RFI on data capture.

6. International coordination and capacity.

a. Designing the overall domestic emergency clinical trials effort in a way that coordinates with international clinical research efforts. It would be helpful to receive comments on how to facilitate the participation of foreign-run clinical trial networks and other foreign bodies in coordinated, large-scale emergency clinical trial protocols initiated by the U.S.

b. Methods for identifying international sites that might be available to participate in emergency clinical trials, including international sites associated with U.S.-run networks as well as foreign-run international sites.

c. Overcoming regulatory barriers that delay expansion of U.S. trials into international sites, or otherwise interfere with clinical research across borders.

d. The best way to track the clinical trial research initiatives being pursued under the G7 Trials Charter and Quad leaders' commitment to pandemic preparedness, and to harmonize U.S. emergency clinical trials efforts with these international initiatives.

Dated: October 19, 2022.

Stacy Murphy,

Operations Manager.

[FR Doc. 2022–23110 Filed 10–25–22; 8:45 am]

BILLING CODE 3270–F1–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96113; File No. SR–OCC–2021–802]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing of Partial Amendments No. 1, 2, 3, and 4 and Notice of No Objection to Advance Notice, as Modified by Partial Amendments No. 1, 2, 3, and 4 Relating to OCC's Adoption of Cloud Infrastructure for New Clearing, Risk Management, and Data Management Applications

October 20, 2022.

I. Introduction

On October 8, 2021, the Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''Commission'') advance notice SR–OCC–2021–802 (''Advance Notice'') pursuant to Section 806(e)(1) of Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act, entitled Payment, Clearing and Settlement Supervision Act of 2010 (''Clearing Supervision Act''),[1] and Rule 19b–4(n)(1)(i)[2] under the Securities Exchange Act of 1934 (''Exchange Act''),[3] in connection with a proposed adoption of third-party-hosted cloud infrastructure (also generally referred to as the ''Cloud'') for OCC's new clearing, risk management, and data management applications. On November 2, 2021, the Commission published notice of the Advance Notice in the **Federal Register** to solicit public comment and to extend the review period for the Advance Notice.[4] The Commission has received no comments regarding the changes proposed in the Advance Notice.

On November 16, 2021, OCC filed Partial Amendment No. 1 to the Advance Notice.[5] On December 13, 2021, OCC filed Partial Amendment No. 2 to the Advance Notice.[6] On July 1, 2022, OCC filed Partial Amendment No. 3 to the Advance Notice.[7] On September 12, 2022, OCC filed Partial Amendment No. 4 to the Advance Notice.[8]

On January 27, 2022, the Commission requested that OCC provide it with additional information regarding the Advance Notice, pursuant to Section 806(e)(1)(D) of the Clearing Supervision Act,[9] which tolled the Commission's period of review of the Advance Notice until 120 days[10] from the date the requested information was received by the Commission.[11] The Commission received OCC's response to the Commission's request for additional information on March 3, 2022.[12] On

[1] 12 U.S.C. 5465(e)(1).

[2] 17 CFR 240.19b–4(n)(1)(i).

[3] 15 U.S.C. 78a *et seq.*

[4] Securities Exchange Act Release No. 93433 (Oct. 27, 2021), 86 FR 60503 (Nov. 2, 2021) (File No. SR–OCC–2021–802) (''Notice of Filing'').

[5] Partial Amendment No. 1 appended an Exhibit 2 to documents previously filed as part of the Advance Notice on October 8, 2021. The Exhibit 2 consists of a communication from OCC to its Clearing Members concerning the changes discussed in the Advance Notice. Partial Amendment No. 1 did not change the purpose of or basis for the Advance Notice.

[6] Partial Amendment No. 2 replaced confidential Exhibits 3f and 3g previously filed as part of the Advance Notice on October 8, 2021 with revised confidential Exhibits 3f and 3g and added new confidential Exhibit 3gg to the Advance Notice. Exhibits 3f and 3gg are two of the documents that collectively comprise the agreement with the Cloud service provider (''CSP'') and were updated as OCC further negotiated and modified the terms of that agreement. Exhibit 3g provides a summary of the terms and conditions of OCC's agreement with the CSP designed to enable OCC to comply with Regulation SCI. Partial Amendment No. 2 did not change the purpose of or basis for the Advance Notice.

[7] Partial Amendment No. 3 replaced the revised confidential Exhibits 3f and 3g that were previously filed in connection with Partial Amendment No. 2 with further revised confidential Exhibits 3f and 3g and added new confidential Exhibit 3hh to the Advance Notice. Exhibit 3hh is a Gantt chart regarding OCC's Cloud transition plan. Partial Amendment No. 3 did not change the purpose of or basis for the Advance Notice.

[8] Partial Amendment No. 4 again replaced confidential Exhibit 3f filed as part of the Advance Notice, as modified by Partial Amendments Nos. 2 and 3, with revised confidential Exhibit 3f. Partial Amendment No. 4 did not change the purpose of or basis for the Advance Notice.

[9] 12 U.S.C. 5465(e)(1)(D).

[10] The Commission may extend the review period for an additional 60 days (to 120 days total) for proposed changes that raise novel or complex issues. *See* 12 U.S.C. 5465(e)(1)(H).

[11] *See* 12 U.S.C. 5465(e)(1)(E)(ii) and (G)(ii); Memorandum from Office of Clearance and Settlement, Division of Trading and Markets, titled ''Commission's Request for Additional Information'' (Jan. 27, 2022), *available at https://www.sec.gov/comments/sr-occ-2021-802/srocc2021802-20113044-265605.pdf.*

[12] *See* Memorandum from Office of Clearance and Settlement, Division of Trading and Markets, titled ''Response to the Commission's Request for