effective on January 23, 2017.[6] EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 4 office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

IV. Proposed Action

EPA is proposing to approve the aforementioned changes to the Chattanooga portion of the Tennessee SIP because the changes are consistent with section 110 of the CAA. The SIP revision adds, clarifies, and updates Rule 6 consistent with applicable requirements.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. This action merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: November 13, 2019.

Mary S. Walker,

Regional Administrator, Region 4.

[FR Doc. 2019–25287 Filed 11–22–19; 8:45 am]

BILLING CODE 6560–50–P

[6] EPA's approval also includes regulations/ordinances submitted for the other ten jurisdictions within the Bureau. *See* footnote 2 and 4, *supra.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 71

[CDC Docket No. CDC–2019–0063]

RIN 0920–AA72

Control of Communicable Diseases; Importation of Human Remains

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

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) proposes to amend two provisions within its foreign quarantine regulations to provide additional clarity and safeguards to address the risk to public health from the importation of human remains into the United States.

DATES: Written or electronic comments on the NPRM must be received by January 24, 2020.

Paperwork Reduction Act Public Comments: Submit written or electronic comments by January 24, 2020. Please see the Paperwork Reduction Act section for instructions on how to submit comments.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0063 or RIN 0920–AA72 by either of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H16–4, Atlanta, GA 30329, ATTN: Human Remains NPRM.

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

Comments will also be available for public inspection from Monday through Friday, except for legal holidays, from 9 a.m. to 5 p.m., Eastern Daylight Time, at 1600 Clifton Road NE, Atlanta, Georgia 30329. Please call ahead to 404–498–1600 and ask for a representative from the Division of Global Migration and Quarantine (DGMQ) to schedule your visit.

FOR FURTHER INFORMATION CONTACT: For information regarding this NPRM: Ashley C. Altenburger, J.D., Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–H16–4, Atlanta, GA 30329. For information regarding CDC operations related to this NPRM: ATTN: Kendra Stauffer, D.V.M., Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–V–18–2, Atlanta, GA 30329. Either may also be reached by telephone 404–498–1600 or email *dgmqpolicyoffice@cdc.gov.*

SUPPLEMENTARY INFORMATION: The NPRM is organized as follows:

I. Public Participation

Interested persons or organizations are invited to participate in this rulemaking by submitting written views, recommendations, and data on all aspects of the proposed rule. Comments received should reference a specific portion of the rule, and inclusion of any attachments and other supporting materials are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. HHS/CDC will carefully consider and address all comments submitted and may revise the content of the rule as appropriate at the final rulemaking stage. HHS/CDC will publish a final rule after the comment period that reflects any content changes made as a result of comments received.

II. Background and Legal Authority

The primary legal authorities supporting this rulemaking are sections 361 and 362 of the Public Health Service Act (42 U.S.C. 264 and 265). Section 361 authorizes the Secretary [1] of HHS to make and enforce such regulations as in the Secretary's judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the states or possessions of the United States or from one state or possession into any other state or possession.

Section 361(a) (42 U.S.C. 264(a) does not limit the types of communicable diseases for which regulations may be enacted, but applies to all communicable diseases that may impact human health. Section 361(a) also authorizes the Secretary to promulgate and enforce a variety of public health regulations to prevent the spread of communicable diseases including regulations relating to: Inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be sources of dangerous infection to human beings, and other measures.

CDC regulations currently define ''communicable disease'' as an illness due to a specific infectious agent or its toxic products which arises through transmission of that agent or its products from an infected person or animal or a reservoir to a susceptible host, either directly or indirectly through an intermediate animal host, vector, or the inanimate environment. *See* 42 CFR 70.1 and 71.1. HHS/CDC is not proposing any changes to this definition but has included this information for background only.

Under 42 CFR 71.55, CDC's Division of Global Migration and Quarantine (CDC/DGMQ) regulates human remains that are imported into the United States primarily for burial, entombment, or cremation (hereinafter ''final resting''). CDC/DGMQ is also authorized under 42 CFR 71.32(b) to take public health measures, including detention, at ports of entry whenever there is ''reason to believe that any arriving carrier or article or thing onboard a carrier is or may be infected or contaminated with a communicable disease.'' Under the authority of 42 CFR 71.32(b) and 42 CFR 71.55, CDC has issued guidance regarding the importation of human remains.[2]

Under the authority of 42 CFR 71.54, CDC's Division of Select Agents and Toxins (CDC/DSAT) issues permits for imported infectious biological agents, infectious substances, and vectors (which includes human remains and body parts) that are known to or reasonably suspected of containing an infectious biological agent.

Section 362 (42 U.S.C. 265) authorizes the HHS Secretary [3] to issue regulations authorizing the suspension of entries and imports into the United States based on the presence of a communicable disease in a foreign country or place.

Regulations at 42 CFR 71.63 authorize the CDC Director to suspend entries and imports into the United States of animals, articles, or things from designated foreign countries or places whenever the Director determines that such an action is necessary to protect public health. Such an action must be based on a finding that there exists in a foreign country or place a communicable disease that would threaten U.S. public health and that the entry or import of that animal, article, or thing from that country or place increases the risk that the communicable disease may be introduced, transmitted, or spread into the United States. Under such circumstances, the Director will designate the foreign countries or places and the period of time or conditions under which the introduction of imports into the United States will be suspended.

HHS/CDC recognizes that other Federal agencies may have equities in the importation or transportation of human remains or other infectious substances. These other Federal agencies include the U.S. Department of Defense (DOD), which oversees the repatriation of remains of U.S. service personnel; the U.S. Department of State (DOS), which assists in the repatriation of remains of U.S. citizens who die overseas; the Department of Transportation, which oversees transportation safety, including the transportation of hazardous materials; and the Department of Homeland Security (DHS), Transportation Security Administration (TSA) which oversees a variety of activities relating to transportation security. Nothing in this NPRM is intended to alter or conflict with statutory provisions, regulations, orders, or directives of these agencies.

III. Rationale for Notice of Proposed Rulemaking

HHS/CDC's role is to ensure that human remains imported into the United States do not contain a communicable disease or an infectious biological agent that could threaten public health. In recent years, HHS/CDC has received an increased number of notifications regarding the importation of body parts that are improperly packaged (*e.g.,* contained in garbage bags or coolers susceptible of leaking fluid) or that lack proper documentation (*e.g.,* importers stating only that the remains are to be used for ''training.'').[4] [5] [6] In some cases, importers have misrepresented the contents of the

[1] 42 U.S.C. 264 and 265 by their terms grant authority to the U.S. Surgeon General. The Reorganization Plan No. 3 of 1966 abolished the Office of the Surgeon General and transferred the Surgeon General's functions to the Secretary of Health, Education, and Welfare (now Secretary of HHS). 31 FR 8855, 80 Stat. 1610 (Jun. 25, 1966). The Secretary of Health, Education, and Welfare was re-designated the Secretary of Health and Human Services by section 509(b) of Public Law 96–88, 93 Stat. 695 (codified at 20 U.S.C. 3508(b)). Although the Office of the Surgeon General was re-established in 1987, the Secretary of HHS has retained the Secretary's authorities under 42 U.S.C. 264 and 265.

[2] *https://www.cdc.gov/importation/human-remains.html.*

[3] The functions of the President under sections 362 and 364(a) of the Public Health Service Act (42 U.S.C. 265 and 267(a)) have been assigned to the HHS Secretary. *See* Exec. Order 13295 (Apr. 4, 2003), as amended by Exec. Order 13375 (Apr. 1, 2005) and Exec. Order 13674 (July 31, 2014).

[4] *https://www.washingtonpost.com/news/morning-mix/wp/2016/03/26/the-husband-and-wife-duo-who-allegedly-dismembered-diseased-bodies-and-sold-them-for-profit/.*

[5] *https://www.reuters.com/investigates/special-report/usa-bodies-brokers/.*

[6] *See also data in economic analysis below.*

package or the remains were found to be leaking.

HHS/CDC has two regulatory provisions that control the safe importation of human remains into the United States:

- Under § 71.54, CDC requires an import permit for the importation of a whole body or body part that is known to contain or reasonably suspected of containing an infectious biological agent.
- Under current § 71.55, CDC requires that imported human remains be cremated, or properly embalmed and placed in a hermetically sealed casket, or accompanied by a permit issued by the CDC Director if the cause of death was a quarantinable communicable disease.

Because both § 71.54 and 71.55 are applicable to imported human remains, U.S. Customs and Border Protection (CBP) agents often hold bodies and body parts for several days at the port of entry until a determination is made as to which regulatory provision should apply. In the past, while CDC has published guidance to its website, it now believes that further rulemaking is needed to address these concerns. Therefore, HHS/CDC is now proposing to formally amend its regulations to codify current policy, to clarify roles and responsibilities, and to better inform importers what requirements may apply, including when a permit may be needed. These changes are not intended to affect the operations of other Federal partners who have equities in either the importation of human remains or the regulation of such imports.

IV. Summary of Notice of Proposed Rulemaking

A. 71.50 Scope and Definitions

Through this NPRM, HHS/CDC is proposing to include four new definitions under 42 CFR 71.50, *Scope and definitions,* which is applicable to importations under part 71 subpart F: ''death certificate,'' ''human remains,'' ''importer,'' and ''leak-proof container.'' We welcome public comment on all proposed definitions.

HHS/CDC proposes to define *death certificate,* for purposes of this regulation, to mean an official government document that certifies that a death has occurred and provides identifying information about the deceased, including (at a minimum) name, age, and sex. The document must also certify the time, place, and cause of death (if known). If the official government document is not written in English, then it must be accompanied by an English language translation of the official government document, the authenticity of which has been attested to by a person licensed to perform acts in legal affairs in the country where the death occurred. In lieu of a death certificate, a copy of the Consular Mortuary Certificate and the Affidavit of Foreign Funeral Director and Transit Permit, shall together constitute acceptable identification of human remains.

By clearly enumerating these data elements, HHS/CDC will be better able to verify a body being imported for final resting matches the description on the death certificate. Further, by proposing to require that the document either be written in English or accompanied by a translation, this definition will facilitate importation into the U.S. CDC will work with DOS to the ensure that the Consular Mortuary Certificate continues to identify whether the individual died of a communicable disease so that a public health risk assessment can be conducted before importation.

HHS/CDC proposes to define *human remains,* for purposes of this regulation, to mean a deceased human body or any portion of a deceased human body, except:

- Clean, dry bones or bone fragments; human hair; teeth; fingernails or toenails; or
- A deceased human body and portions thereof that have already been fully cremated prior to import; or
- Human cells, tissues or cellular or tissue-based products (HCT/Ps) intended for implantation, transplantation, infusion, or transfer into a human recipient.

This proposed definition excludes clean, dry bones or bone fragments, human hair, teeth, fingernails or toenails and fully cremated bodies or portions thereof because these items do not contain body fluids and therefore are not considered to pose a threat to public health. By narrowing this definition, HHS/CDC is also able to convey which portions of the dead body it intends to regulate. For purposes of this regulation, the proposed definition also excludes HCT/Ps intended for implantation, transplantation, infusion, or transfer into a human recipient because these items are regulated by a separate HHS agency (the Food and Drug Administration).

HHS/CDC proposes to define *importer,* for purposes this regulation, as any person importing or attempting to import an item regulated under the subpart.

This proposed definition will be applicable to all provisions under subpart F of 42 CFR part 71. ''Person'' is currently defined under § 71.50 as any individual or partnership, firm, company, corporation, association, organization, or similar legal entity, including those that are not-for-profit. No changes will be made to the definition of ''Person.''

HHS/CDC is proposing to replace the current requirement that remains be contained within a ''hermetically sealed casket'' with a requirement and definition of *leak-proof container,* defined for the purposes of this regulation, as a container that is puncture-resistant and sealed in a manner so as to contain all contents and prevent leakage of fluids during handling, storage, transport, or shipping, such as:

- A double-layered plastic, puncture-resistant body bag (*i.e.,* two sealed body bags, one inside the other),
- A casket with an interior lining certified by the manufacturer to be leak-proof and puncture-resistant, or
- A sealed metal body-transfer case.

This will ensure that importers are aware that coolers, garbage bags, and similar non-leak-proof containers are not acceptable because these items do not prevent the leakage of fluids used to transport human remains.

B. 71.55 Importation of Human Remains

To best reflect current practice, HHS/CDC proposes to rename current 42 CFR 71.55 ''Dead Bodies'' to ''Importation of Human Remains'' to clarify that our authority extends to portions of the human body, and not only to ''dead bodies'' as a whole, as well as to highlight the difference in documentation needed between human remains imported for final resting (under § 71.55) and human body parts primarily imported for other reasons, which may fall under § 71.54 ''Import regulations for infectious biological agents, infectious substances, and vectors.''

Under proposed 42 CFR 71.55(a), all human remains intended for import into the United States and those transiting through the United States *en route* to a foreign destination must be contained in a leak-proof container that is packaged and shipped in accordance with all applicable legal requirements. This requirement will ensure that individuals handling the packages of human remains are not exposed to body fluids that may contain an infectious biological agent or embalming material, regardless of whether the remains are intended for importation or are in transit through the United States. HHS/CDC also proposes to eliminate specific requirements under current § 71.55 that

human remains of a person who died of a quarantinable communicable disease be ''embalmed'' and placed into a ''hermetically sealed casket'' because this no longer reflects current best practices and unnecessarily increases the burden on importers.

Proposed § 71.55(b) informs the public that imports of human remains known to contain or reasonably suspected of containing an infectious biological agent must abide by 42 CFR 71.54 to ensure that all measures are taken to protect U.S. public health. This includes remains known to contain or reasonably suspected of containing an infectious biological agent that have not or cannot be rendered noninfectious.

Under proposed § 71.55(c)(1)(i), to ensure that human remains imported for final resting enter only for the intended purpose, we have included a proposed requirement that such remains be consigned ''directly'' to a licensed mortuary, cemetery, or crematory. Section 71.55(c)(1)(ii), requires that these remains (unless embalmed) must also be accompanied by a death certificate or, if the death certificate is incomplete or missing, an importer certification statement confirming that the human remains are not known to contain or stating why the human remains are not reasonably suspected of containing an infectious biological agent. Such documentation ensures that the human remains do not pose a threat to public health because the decedent succumbed to a communicable disease, including a quarantinable communicable disease.

HHS/CDC is aware that certain Federal partners, such as DOD and DOS, may require that human remains of military or civilian personnel continue on to a place of final resting outside of the United States after the remains are transported into the United States. Such a transport will not be deemed an ''import'' under this provision and therefore will not be subject to the requirement that remains be consigned ''directly'' to a licensed mortuary, cemetery, or crematory, because the remains are ''transiting'' through the United States *en route* to final destination. Under this proposal, HHS/CDC will not prevent human remains from transiting through a U.S. port of entry *en route* to another country, provided that the remains are properly packaged in a leak-proof container and in compliance with applicable transportation requirements.

Under proposed § 71.55(c)(2)(i), if human remains are imported for medical examination or autopsy, the remains must be consigned directly to an entity authorized to perform such functions under the laws of the applicable jurisdiction prior to subsequent burial, entombment, or cremation. By ''authorized,'' HHS/CDC includes government entities that typically perform medical examinations or autopsies such as state or local coroners' offices, as well as private entities operating in compliance with the laws of the relevant jurisdiction. Upon completion of the medical examination or autopsy, the human remains must be immediately delivered to a licensed mortuary, cemetery, or crematory that will be responsible for final resting. Section 71.55(c)(2)(ii), requires that these remains (unless embalmed) be accompanied by a death certificate or, if the death certificate is incomplete or missing, an importer certification statement confirming that the human remains are not known to contain or stating why the human remains are not reasonably suspected of containing an infectious biological agent. Such documentation ensures that the human remains being imported do not pose a threat to public health because the decedent succumbed to a communicable disease, including a quarantinable communicable disease.

Both § 71.55(c)(1) and (2) include the clause ''unless embalmed'' because embalmed remains are considered to have been rendered noninfectious and therefore would not require a death certificate to ensure that the individual did not die of a communicable disease. HHS/CDC understands that certain countries do not state cause of death on a death certificate due to privacy concerns. For this reason, also under proposed § 71.55(c)(1) and (2), if the death certificate is incomplete or if cause of death is not listed, the human remains must be accompanied by an importer certification statement confirming that the human remains are not known to contain or reasonably suspected of containing an infectious biological agent.

CDC will also deem a consular mortuary certificate that references whether the person died of a communicable disease, accompanied by an affidavit or sworn declaration by the local funeral director and transit permit, together as sufficient documentation in lieu of a death certificate. CDC welcomes public comment on whether other valid documents should be accepted in lieu of a death certificate.

Proposed § 71.55(c)(3) requires that, unless embalmed, all ''human remains'' (as that term is defined) imported into the United States for purposes other than final resting or autopsy be accompanied by an importer certification statement confirming that the human remains are not known to contain or stating why the human remains are not reasonably suspected of containing an infectious biological agent. This proposed language addresses the other uses for human remains such as medical training or anatomical display.

HHS/CDC understands that certain partner agencies, such as the FAA Civil Aerospace Medical Institute (CAMI), may import human remains in order to help accident investigators determine the cause and contributing factors of an aircraft accident. Performing toxicology and other medical tests on human remains, as well as reviewing medical records, toxicological testing results, and autopsy reports, can help accident investigators determine, for example, if an airman's medical impairment or incapacitation contributed to the cause of an aircraft accident. HHS/CDC does not consider importations of human remains for these purposes to constitute ''human remains imported for medical examination or autopsy'' because the purpose is not to determine individual cause of death, but rather to aid in accident investigation. In addition, other organizations may import cadavers or partial human remains for product or safety testing or other scientific purposes. Human remains imported for these purposes would fall under the ''imported for any other purpose'' under (c)(3) and would require, unless embalmed, an importer certification statement confirming that the human remains are not known to contain or stating why the human remains are not reasonably suspected of containing an infectious biological agent.

Finally, under proposed § 71.55(d), the CDC Director may suspend the entry or importation of human remains under 42 CFR 71.63 if the Director determines that such an action is necessary to protect the public health. Such an action may occur when (i) the import is coming from a foreign country designated by the CDC Director as a place where a communicable disease exists that could threaten U.S. public health and (ii) the import increases the risk of introducing or spreading the communicable disease into the United States. In the past, this provision has only been invoked to temporarily suspend wildlife reservoirs of zoonotic disease and HHS/CDC does not anticipate that this provision will be invoked frequently absent a public health emergency where such measures would be needed to protect U.S. public health. HHS/CDC welcomes public comment on this proposed emergency measure.

VI. Required Regulatory Analyses

A. Executive Orders 12866 and 13563

Executive Orders 12866 ''Improving Regulation and Regulatory Review,'' and 13563, ''Regulatory Planning and Review,'' direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Statement of Need

As discussed in more detail above, HHS/CDC proposes to amend two provisions within its foreign quarantine regulations (specifically, 42 CFR 71.50 and 71.55) to provide additional clarity and safeguards to address the risk to public health from the importation of human remains into the United States. In recent years, HHS/CDC has received an increased number of notifications regarding the importation of body parts that are improperly packaged (*e.g.,* contained in garbage bags or coolers susceptible of leaking fluid) or that lack proper documentation (*e.g.,* importers stating only that the remains are to be used for ''training.'').[7] [8] In some cases, importers have misrepresented the contents of the package or the remains were found to be leaking.

HHS/CDC has two regulatory provisions that control the safe importation of human remains into the United States:

- Under § 71.54, CDC requires an import permit for the importation of a whole body or body part that is known to contain or reasonably suspected of containing an infectious biological agent.
- Under current § 71.55, CDC requires that imported human remains be cremated, or properly embalmed and placed in a hermetically sealed casket, or accompanied by a permit issued by the CDC Director if the cause of death was a quarantinable communicable disease.

Because both §§ 71.54 and 71.55 are applicable to imported human remains, CBPU.S. Customs and Border Protection agents often hold bodies and body parts for several days at the port of entry until a determination is made as to which regulatory provision should apply. In the past, while CDC has published guidance to its website, it now believes that further rulemaking is needed to address these concerns. Therefore, HHS/CDC is now proposing to formally amend its regulations to codify current policy, to clarify roles and responsibilities, and to better inform importers what requirements may apply, including when a permit may be needed. These changes are not intended to affect the operations of other Federal partners who have equities in either the importation of human remains or the regulation of such imports.

The proposed regulatory changes described in the preamble and reported below are a codification of current requirements authorized under existing 42 CFR 71.32(b), 71.54, 71.55, and 71.63, and described in guidance. Since this NPRM does not change the regulatory baseline, HHS/CDC expects minimal economic impacts on importers of human remains, Department of Homeland Security/Customs and Border Protection/Transportation Security Administration (DHS/CBP, DHS/TSA,), HHS/CDC, Department of State (DOS), airline or other industries that facilitate the importation of human remains, or state and local public health departments (Ph.D.s).

HHS/CDC regulations are necessary to correct the market failure in which human remains are improperly packaged (*e.g.,* contained in garbage bags or coolers susceptible of leaking fluid) or that lack proper documentation that could pose additional risk to individuals in the event of an accidental exposure. These changes should reduce risks of exposure for other non-importer stakeholders (*e.g.,* carrier or vessel staff, other travelers, TSA or CBP staff who inspect cargo) to communicable diseases. The container requirement limits exposures to leaking fluids. The documentation requirements ensure that human remains that pose a public health risk are accompanied with the proper permit documentation under existing 42 CFR 71.54 or are consigned ''directly'' to a licensed mortuary, cemetery, or crematory. If human remains are consigned directly to a licensed mortuary, cemetery, or crematory, the human remains will be handled by professionals with experience handling human remains. Otherwise, the documentation and container requirements would limit others' exposure to human remains or may provide additional information (via the documentation requirements) on potential public health risks in the event of an exposure.

The requirements specified under proposed 42 CFR 71.55(a) conform with existing CDC guidance that human remains should be transported in a leak-proof container that is packaged and shipped in accordance with all applicable legal requirements. For human remains for which the cause of death was a quarantinable communicable disease, HHS/CDC requirements will change from the more restrictive hermetically sealed casket to the less restrictive leakproof container. These requirements are also consistent with requirements imposed by the four largest U.S. carriers in 2019 for transport of human remains (*i.e.,* Delta, American, United, and Southwest Airlines). In practice, HHS/CDC is unaware of any imported human remains of individuals who died of a quarantinable disease in the previous 15 years. HHS/CDC proposes to eliminate specific requirements under current § 71.55 that human remains of a person who died of a quarantinable communicable disease be ''embalmed'' and placed into a ''hermetically sealed casket'' because this no longer reflects current best practices and would unnecessarily increase the burden on importers.

The requirements under proposed 42 CFR 71.55(b) simply refer to existing permit requirements described in 42 CFR 71.54 for all imported human remains known to contain or reasonably suspected of containing an infectious biological agent. There is no change to 42 CFR 71.54, simply clarification of when 42 CFR 71.54 should apply to transport of human remains. The requirements under proposed 42 CFR 71.55(c) clarify the documentation requirements for un-embalmed human remains imports that do not need permits according to existing 42 CFR 71.54. These documentation requirements are consistent with existing practices in the Department of State's Foreign Affairs Manual and consistent with other agencies' requirements for transporting human remains to facilitate U.S. Customs Clearance.

HHS/CDC qualitatively considered alternatives to codifying current practice. HHS/CDC considered a less-restrictive requirement than transport of human remains in a leakproof container. Qualitatively, HHS/CDC does not believe this regulatory action would significantly change the current status quo. As noted, the current requirements of the four largest U.S. carriers to ship human remains are already consistent with the HHS/CDC's leakproof container requirement. If HHS/CDC chose not to

[7] *https://www.washingtonpost.com/news/morning-mix/wp/2016/03/26/the-husband-and-wife-duo-who-allegedly-dismembered-diseased-bodies-and-sold-them-for-profit/.*

[8] *https://www.reuters.com/investigates/special-report/usa-bodies-brokers/.*

regulate the type of container, airlines may choose to maintain their existing requirement for transporting human remains internationally in leakproof containers to avoid exposures to their employees, which may also be regulated, after entry through ports of entry, under the U.S. Department of Labor's Occupational Safety and Health Administration's requirements (refer to 29 CFR 1910.1030). In addition, importers (other than colleges, hospitals, or laboratories) of human remains for purposes other than burial, entombment, or cremation may already be subject to U.S. Department of Transportation packaging requirements delineated in 49 CFR 173.199. These requirements are more restrictive than HHS/CDC's leakproof container requirement.

Another alternative would be to require a more restrictive requirement, such as a hermetically sealed casket, to import all un-embalmed human remains. Qualitatively, the cost of this alternative would be much more expensive than the status quo guidance and HHS/CDC does not believe the marginal improvement to public health would justify the substantially increased cost of requiring hermetically sealed caskets to import all un-embalmed human remains.

HHS/CDC documentation requirements are consistent with existing international agreements and instruments governing the international transportation of human remains as noted in the DOS Foreign Affairs Manual, 7 FAM 252(b).[9] The documentation requirements listed in proposed 42 CFR 71.55(c) only apply to human remains that are not embalmed. Since the majority of human remains imported for burial, entombment, or cremation are embalmed, most importations would not be affected by this codification of current practice.

A less restrictive alternative would be to also omit the documentation requirements for un-embalmed human remains. However, as noted in 7 FAM 258, DOS states that the consular mortuary certificate is designed to facilitate U.S. Customs Clearance. In addition, DOS requests a certificate of death, an affidavit by the local funeral director, and a transit permit as required by local laws to support exporting human remains. It should be noted that the documentation requested by DOS to support the transportation of cremated human remains (which are exempt from HHS/CDC requirements) are similar to the requested documentation for non-cremated human remains.[10] In general, HHS/CDC would expect that death certificates or the Affidavit of Foreign Funeral Director and Transit Permit would be created in the event of an overseas death and would be available for most human remains imported for burial, entombment, or cremation. However, it may not be necessary to provide either a (translated) death certificate or to translate the Affidavit of Foreign Funeral Director or Transit Permit. Thus, the primary cost may be for translation services for these documents if human remains are imported from a non-English-speaking country. Since the importation of most human remains are already facilitated by DOS consular offices, translated documentation may already be provided to U.S. consular offices in most cases. Without the documentation required in this NPRM, it would not be possible for HHS/CDC to confirm that individuals did not die from a quarantinable communicable disease or otherwise pose a public health risk to individual exposed to their un-embalmed remains. In the past, HHS/CDC has not routinely had issues obtaining these documents for imported, un-embalmed human remains for burial, entombment, or cremation in the past, but would welcome public comment on the cost of producing such documentation. Qualitatively, HHS/CDC believes that the costs associated with increased risk of exposure to un-embalmed human remains infected with communicable diseases justify the expense for the documentation requirements codified in proposed 42 CFR 71.55(c) for un-embalmed human remains.

A more restrictive documentation requirement would be to require that all importations of human remains (*i.e.,* embalmed remains as well as un-embalmed remains) comply with this documentation requirement. However, HHS/CDC does not believe that the public health risks posed by embalmed human remains (*e.g.* exposure to embalming fluids) shipped in leakproof containers necessitate additional documentation requirements for public health purposes.

HHS/CDC also considered an alternative in which different requirements would apply to different countries. However, since most human remains that are imported to the United States were U.S. citizens, permanent residents, or their relatives, HHS/CDC does not generally believe the risk of exposure to communicable diseases is likely to vary depending based on the country from which human remains are imported. HHS/CDC does address the potential need to apply different requirements to different countries in proposed 42 CFR 71.55(d). The CDC Director may suspend the entry or importation of human remains under 42 CFR 71.63 if the Director determines that such an action is necessary to protect the public health. Such an action may occur when (i) the import is coming from a foreign country designated by the CDC Director as a place where a communicable disease exists that could threaten U.S. public health and (ii) the import increases the risk of introducing or spreading the communicable disease into the United States. In the past, this provision has only been invoked to temporarily suspend wildlife reservoirs of zoonotic disease and HHS/CDC does not anticipate that this provision will be invoked frequently absent a public health emergency where such measures would be needed to protect U.S. public health.

The rest of the economic evaluation below focuses on estimation of the potential costs and benefits of the requirements included in this NPRM relative to the current status quo.

Economic Impact

DOS works with U.S. residents to process the required documentation for importing human remains into the United States for burial, entombment, or cremation. Their requirements are reported in the current version of the Foreign Affairs Manual (FAM). In 7 FAM 252(a)(3), DOS notes that CDC's authority is not limited to quarantinable communicable diseases but extends to the importation of remains of persons who died of other communicable diseases. Specifically, 7 FAM 252(a)(3) states that ''In general, U.S. public health requirements will be satisfied if the remains are shipped in a leak-proof container and accompanied by the death certificate or the consular mortuary certificate, which must state that the deceased did not die from a quarantinable communicable disease. A leak-proof container is one that is puncture-resistant and sealed in a manner to contain all contents and prevent leakage of fluids during handling, storage, transport, or shipping. While additional restrictions are not generally employed, CDC reserves the right to do so on a case-by-

[9] The international agreements and instruments listed in 7 FAM 252(b) are (1) Council of Europe, Agreement on The Transfer Of Corpses, Signed at Strasbourg, October 26th, 1973; (2) Pan American World Health Organization, XVII Pan American Sanitary Conference, XVIII Regional Committee Meeting, Resolution XXIX, adopted in Washington, October 7th, 1966, International Transportation Of Human Remains; and (3) International Arrangements Concerning the Conveyance of Corpses, Signed at Berlin, February 10, 1937.

[10] Refer to 7 FAM 256.

case basis when necessary to prevent the spread of disease.''

This description is consistent with the codification of requirements of human remains for the purposes of burial, entombment, or cremation under proposed 42 CFR 71.55 as summarized above. Because this is a codification of current practice, the economic impact on importers of human remains and DOS are expected to be minimal. To estimate the cost to DOS to update the FAM to include references to proposed 42 CFR 71.55, the cost was estimated by assuming that 1 GS–14, step 5 employee and one GS–15, step 5 employee each spend 40 hours (*i.e.,* 80 hours in total) for any updates to cite the language in proposed 42 CFR 71.55. The hourly wage rates for these two employees based in Washington-Baltimore-Arlington, DC-MD-VA-WV-PA are $62.23 (GS–14) and $73.20 (GS–15).[11] To account for the non-wage benefits, we multiplied the wage cost by two to result in a total cost estimate of $10,834. The costs for CBP and CDC are expected to be similar (Table 1), because this change is a codification of current practice. Thus, the expected one-time costs associated with codification for all three agencies can be estimated at $31,906.

TABLE 1—SUMMARY OF THE ONE-TIME COSTS IN 2018 USD TO UPDATE OFFICIAL DOCUMENTS FOR DEPARTMENT OF STATE (DOS), CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC), AND CUSTOMS AND BORDER PROTECTION (CBP) COSTS FROM THE CODIFICATION IN PROPOSED 42 CFR 71.55 OF THE REQUIREMENTS AUTHORIZED UNDER EXISTING 42 CFR 71.32(b), 71.54, AND 71.63

Agency	Cost components	Hourly wage rate [12]	Multiplier for non-wage benefits and overhead	Total
DOS	80 hours split between GS–14, step 5 and GS–15, step 5 levels	67.72	2	$10,834
CDC	80 hours split between GS–14, step 5 and GS–15, step 5 levels	63.99	2	10,238
CBP	80 hours split between GS–14, step 5 and GS–15, step 5 levels	67.72	2	10,834
Total				$31,906

Individuals importing human remains for purposes other than burial, entombment, or cremation, may be less familiar with CDC requirements authorized under existing 42 CFR 71.32(b) and 71.54. As a result, importers of human remains for other purposes may not be aware of the requirement that human remains must arrive in an appropriate, leak-proof shipping container as specified under proposed 42 CFR 71.55(a). In addition, they may not be aware that, unless human remains are embalmed and therefore rendered noninfectious, they must be accompanied by a death certificate listing cause of death or that if the death certificate is incomplete or if cause of death is not listed, the human remains must be accompanied by an importer certification statement either confirming that the human remains are not known to contain or stating why the human remains are not reasonably suspected of containing an infectious biological agent as specified under proposed 42 CFR 71.55(c). In addition, importers would need to apply for a permit under existing 42 CFR 71.54 if they are unable to demonstrate that human remains are not reasonably suspected of containing an infectious biological agent. Upon publication of a final rule, CDC will update its website to ensure that importers have access to the most up-to-date information regarding packaging and documentation requirements for human remains.

The codification of existing requirements should not result in an additional regulatory burden and should help reduce the costs by reducing confusion regarding the requirements for importing human remains for purposes other than burial, entombment or cremation. However, as an upper bound cost estimate, we assumed that one additional importer would apply for a permit to import human remains for other purposes every other year after the final rule goes into effect. When importers first apply for a permit, the greatest expense is associated with the need for DSAT to perform an inspection of the importers' facilities and to document their findings. This process also requires time for importers to support the inspection and respond to questions from DSAT subject matter experts. HHS/CDC estimated the amount of time per inspection to include about 20 hours of staff time split between the GS–12, GS–13, and GS–14 pay levels. To estimate costs, HHS/CDC assumed the staff would be compensated at step 5 as summarized in Table 2. In addition to hourly wages, non-wage benefits and overhead costs were estimated by multiplying the wage cost by two. The average round trip airfare for flights from Atlanta was estimated at $367 using data from the Bureau of Transportation Statistics.[13] The average Federal per diem for lodging, meals, and incidental expenses was estimated at $158 per day for one day.[14] Assuming that inspections occur on average (0.5 times per year, the annual cost would be estimated at $1,518 per year.

[11] U.S. Office of Personnel and Management. *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2018/general-schedule/.* Accessed on March 27, 2019.

[12] U.S. Office of Personnel and Management. *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2018/general-schedule/.* Accessed on March 27, 2019.

[13] Bureau of Transportation Statistics. Average Domestic Airfares (Atlanta, 2018 Q4). *https://transtats.bts.gov/AIRFARES/.* Accessed on June 19, 2019.

[14] *FederalPay.org.* 2018 Federal Per Diem Rates. (Average of 50 states). *https://www.federalpay.org/perdiem/2018.* Accessed on June 19, 2019.

In addition to CDC costs, importers would have to spend time to support the inspection and respond to CDC questions. HHS/CDC would welcome public comment on the costs to importers to support such inspections. HHS/CDC assumed the amount of time required would be equivalent to CDC staff time (*i.e.,* about 20 hours) and that the individual working on the inspection would be compensated at a rate equivalent to the national average wage rate reported for individuals working as Sales Representatives, Wholesale and Manufacturing, Technical and Scientific Products as reported in the Bureau of Labor Statistics' May 2018 National Occupational Employment and Wage Estimates (Occupation code= 41–4011).[15] Their 2018 reported hourly wage rate was $44.15. Assuming 0.5 inspections per year and a multiplier of 2 to cover non-wage benefits and overhead, the annual cost for importers was estimated at $883 per year. In total, the annual cost for increased inspections for CDC ($1,518) and importers ($883) was estimated at $2,401. This should represent an upper bound estimate as HHS/CDC does not anticipate a large increase in inspections as a result of this NPRM.

TABLE 2—ESTIMATED ANNUAL CDC COST IN 2018 USD FOR INSPECTIONS OF THE FACILITIES FOR AN IMPORTER OF HUMAN REMAINS FOR PURPOSES OTHER THAN FINAL RESTING

Type of CDC staff	Number of staff	Number of inspections per year	Number of hours spent per inspection	Average hourly wage rate [16]	Overhead multi-plier	Annual cost
GS–12 (step 5)	0.33	0.5	20	$41.85	1	$276
GS–13 (step 5)	0.33	0.5	20	49.76	1	328
GS–14 (step 5)	0.33	0.5	20	58.80	1	388
Total						993
Travel cost	Airfare [17]	$367	Hotel, food, lodging [18]		$158	$525
Total (personnel + travel)						1,518

The total projected costs over a 10-year time horizon for each government agency and for importers can be estimated using a 3% discount rate. Table 3 summarizes the present value and annualized value of costs over the full 10-year period. In total, the estimated cost is $46,977 over 10 years or an annualized value of $5,507 per year.

TABLE 3—PRESENT VALUE AND ANNUALIZED VALUE OF COSTS IN 2018 USD OVER 10 YEARS USING A 3% DISCOUNT RATE FOR GOVERNMENT AGENCIES AND FOR IMPORTERS OF HUMAN REMAINS FOR PURPOSES OTHER THAN FINAL RESTING

	Net present cost over 10-year horizon	Annualized cost over 10-year horizon
CDC	$18,408	$2,158
CBP	10,518	1,233
DoS	10,518	1,233
Importers of human remains for other purposes	7,532	883
Total	46,977	5,507

In the past, imported human remains for reasons other than burial, entombment or cremation have arrived in inappropriate (*i.e.,* not leak-proof) containers or without sufficient documentation to determine whether such remains may contain or be reasonably suspected of containing an infectious biological agent. This has led to confusion at the port of entry and detention of the human remains pending an investigation. CDC reviewed available importation records and identified six human remains shipments that required repackaging over the 5-year period from 2014 to 2018. Of the six shipments, four occurred between November 2017 and the end of 2018. These investigations require significant effort to resolve. CDC involvement usually includes scientific, legal, policy, and leadership staff from CDC/DGMQ and CDC/DSAT. In each of these cases, CDC determined that a permit issued according to existing 42 CFR 71.54 would be required when human remains are reasonably suspected of containing an infectious biological agent if they are without adequate shipping containers or proper documentation, unless they are cremated, embalmed, or otherwise rendered noninfectious per the proposed definition of ''human remains.''

Although the amount of time per investigation event varies, on average, each importation investigation was estimated to require approximately 600 hours of CDC staff time split between

[15] Bureau of Labor Statistics, May 2018 National Occupational Employment and Wage Estimates (Occupation code= 41–4011). *https://www.bls.gov/oes/current/oes_nat.htm.* Accessed on June 19, 2019.

[16] U.S. Office of Personnel and Management. *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2018/general-schedule/.* Atlanta-Athens-Clarke county-Sandy Springs, GA–AL Accessed on June 19, 2019.

[17] Bureau of Transportation Statistics. Average Domestic Airfares (Atlanta, 2018 Q4). *https://transtats.bts.gov/AIRFARES/.* Accessed on June 19, 2019.

[18] *FederalPay.org* 2018 Federal Per Diem Rates. (Average of 50 states). *https://www.federalpay.org/perdiem/2018.* Accessed on June 19, 2019.

the GS–13, GS–14, and GS–15 levels. The time spent included conference calls with the importer and CBP, legal review, permit issuance under 42 CFR 71.54, if applicable, among other activities (Table 4). The 2018 reported hourly wage rates for GS–13, GS–14, and GS–15 employees at step 5 are $49.76, $58.80, and $69.17 per hour respectively in the Atlanta, GA area.[19] If this amount of time is split evenly across each level, the estimated cost per investigation would be $35,546. This amount can then be multiplied by 2 to account for non-wage benefits and overhead to estimate a total cost of $71,092 per investigation.

In addition to CDC costs, CBP also incurs costs to deal with each investigation including time spent communicating with CDC. The amount of time spent by CBP is also significant and conservatively estimated at 50% of the time spent by CDC staff. The estimated hourly wage rate for CBP officers was estimated by assuming that the workload would be split evenly across employees at the GS–5, GS–9, GS–11, and GS–12 levels with support from GS–15 managers providing additional coordination with CDC senior staff. Thus, compensation was split evenly across grades and each grade was assumed to be compensated at the step 5 level using the Washington-Baltimore-Arlington hourly pay scale (on average, $41.02 per hour).[20] This would result in a wage cost of $12,306. After multiplying wages by 2 to account for non-wage benefits and overtime, the estimated CBP cost would be $24,614. Adding the CBP and CDC costs, the total cost per investigation event would be $71,092 + $24,614 = $95,706.

TABLE 4—BENEFITS (AVERTED COSTS) PER EVENT IN 2018 USD IN WHICH HUMAN REMAINS WITHOUT ADEQUATE DOCUMENTATION OR SHIPPING CONTAINERS ARE IMPORTED FOR PURPOSES OTHER THAN BURIAL, ENTOMBMENT, OR CREMATION AND ARE HELD AT THE PORT OF ENTRY PENDING AN INVESTIGATION

Agency	Cost components	Hourly wage rate[21]	Multiplier for non-wage benefits and overhead	Total
CDC	600 hours split between GS–13, step 5; GS–14, step 5; and GS–15, step 5 levels.	$59.24	2	$71,092
CBP	300 hours at the GS–5, GS–9, GS–11, GS–12, and GS–15, step 5 level	41.02	2	24,614
Total				95,706

In addition to costs to CDC and CBP, importers of human remains for purposes other than final resting might not use leak-proof containers or fail to provide import permits or importer certification statement(s). When this occurs, importers spend a considerable amount of time communicating with CDC and CBP about missing documentation, searching for missing documentation after those human remains arrive at ports of entry, or repackaging shipments at the importer's expense. This codification of requirements authorized under 42 CFR 71.32(b), 42 CFR 71.54, and 42 CFR 71.55 pertaining to the importation of human remains should reduce confusion. Besides the time spent on searching for documentation and the cost of repackaging, the human remains may begin to decompose during the investigation process, which would affect the value of imports that may otherwise be used for purposes other than final resting. HHS/CDC does not have any way to estimate time for repackaging costs or decomposition costs, but would welcome public comment on these costs. By reducing confusion, some of these costs may be averted when the proposed 42 CFR 71.55 goes into effect. On the other hand, codification of these requirements may increase the costs of human remains for purposes other than burial, entombment, or cremation if such importations are currently occurring without CBP or CDC oversight.

The one-time costs of updating communications materials and the costs for an additional 0.5 importers per year to undergo an inspection to verify their ability to safely import human remains for purposes other than final resting was estimated to cost $46,977 over 10 years (annualized cost: $5,507). These costs can be compared to the benefits (averted costs per investigation after human remains are held at the port of entry because they arrived in a container that was not leak-proof or with improper documentation ($95,706). During calendar years 2014–2018, there were seven time-intensive investigations for an average 1.4 investigations per year. Among these events, one shipment of human remains was re-exported. The remaining six shipments all required repackaging and were held by CBP for between 2 days and 22 days (average hold: 11.3 days). Of the seven total investigations, six involved human remains imported for purposes other than final resting. One of these shipments was re-exported and the other five shipments of human remains were cremated after being held by CBP. Four of the seven investigations occurred in 2018, demonstrating an increasing trend in improperly imported human remains.

A comparison can be made between the estimated costs and potential benefits (*i.e.,* averted Federal Government costs for an investigation). This comparison suggests that even if only one held importation requiring investigation will be averted in the 10 years after the codification goes into effect, the expected benefits (averted costs) would exceed expected costs assuming a discount rate of 3% per year. To the extent that this NPRM would increase the number of inspections by DSAT, the need to conduct investigations should decrease proportionately. This is because it is assumed that the need for investigations results from lack of awareness of importation requirements for human remains for purposes other than final resting as authorized under existing 42 CFR 71.32(b), 42 CFR 71.54 and 42 CFR 71.55. However, the inspection process itself should allow importers to fully understand their import requirements in regard to shipping containers, documentation, or permits.

[19] U.S. Office of Personnel and Management. *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2018/general-schedule/.* Accessed on March 27, 2019.

[20] U.S. Office of Personnel and Management. *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2018/general-schedule/.* Accessed on March 27, 2019.

[21] U.S. Office of Personnel and Management. *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2018/general-schedule/.* Accessed on March 27, 2019.

In addition to the reduced costs associated with imported human remains for purposes other than burial, entombment, or cremation arriving with inadequate documentation or shipping containers, there may be additional savings for the small numbers of human remains that arrive with insufficient documentation for burial, entombment, or cremation. During calendar years 2014 through 2018, CDC requested additional documentation from seven importers of human remains for burial, entombment or cremation (average 1.4 events per year) and 9 importers of human remains for purposes other than final resting (1.8 events per year). In contrast to the time-intensive investigation events described above, these events were usually resolved quickly because death certificates listing cause of death or importer certification statements either confirming that the human remains were not known to contain or stating why the human remains were not reasonably suspected of containing an infectious biological agent were provided relatively quickly. However, delays still incur some additional time costs that may be averted if the requirements codified in proposed 42 CFR 71.55 are better understood.

Finally, the proposed language in 42 CFR 71.55(d) that existing 42 CFR 71.63 may apply to imported human remains, if the Director designates a foreign country and determines that such an action is necessary to protect the public health, is again codifying an existing requirement. Since its enactment, CDC has applied 42 CFR 71.63 one time, on May 10, 2019, to suspend entry of dogs from Egypt after three dogs with canine rabies virus variant were imported into the United States within four years.[22] However, the suspension has not been in place long enough to do a full economic analysis and a suspension of imports for dogs may not be analogous to a suspension of imports for human remains in terms of economic impact.

B. Executive Order 13771

Executive Order 13771 ''Reducing Regulation and Controlling Regulatory Costs,'' requires executive departments and agencies to eliminate at least two existing regulations for every new significant regulation that imposes costs. HHS/CDC has determined that this rule imposes no more than de minimis costs, and therefore not considered a regulatory action.

C. The Regulatory Flexibility Act

Under the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), agencies are required to analyze regulatory options to minimize significant economic impact of a rule on small businesses, small governmental units, and small not-for-profit organizations. HHS/CDC finds that the NPRM is not expected to change the cost of compliance for small businesses, small governmental units, or small not-for-profit organizations.

D. Paperwork Reduction Act of 1995

HHS/CDC has determined that this NPRM contains proposed information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). A description of these proposed provisions is given below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information. Comments are invited on the following subjects.

- Whether the proposed collection of information is necessary for the proper performance of the functions of HHS/CDC, including whether the information will have practical utility.
- The accuracy of HHS/CDC's estimate of the burden of the collection of information.
- Ways to enhance the quality, utility, and clarity of the information to be collected.
- Ways to minimize the burden of the collection of information on respondents, including by using information technology.

HHS/CDC currently has approval to collect certain information concerning the importation of dead bodies under two OMB Control Numbers: 0920–0134 *Foreign Quarantine Regulations* (expiration date 03/31/2022) and 0920–0199 Application for Permit to Import Biological Agents and Vectors of Human Disease into the United States and Application for Permit to Import or Transport Live Bats (42 CFR 71.54) (expiration date 04/30/2021). This NPRM is proposing updates to one information collection: 0920–0134. CDC is taking public comment on the burden to the public outlined in this update.

Written comments should be received within 60 days of the publication of this NPRM. Please send written comments to Information Collection Review Office, 1600 Clifton Road NE, Atlanta, GA 30333.

Proposed Projects

(1) Foreign Quarantine Regulations (42 CFR part 71) (OMB Control No. 0920–0134)—Nonmaterial/non-substantive change—National Center for Emerging, and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Description

Section 361 of the Public Health Service (PHS) Act (42 U.S.C. 264) authorizes the Secretary of Health and Human Services to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States. Legislation and existing regulations governing foreign and interstate quarantine activities (42 CFR parts 70 and 71) authorize CDC quarantine officers and customs personnel to inspect and undertake necessary control measures in order to protect the public's health. Other inspection agencies assist quarantine officers in public health risk assessment and management of persons, animals, and other importations of public health importance, including human remains. Human remains may harbor communicable diseases, and if not packaged and processed according to accepted standards, may represent a risk to handlers and the receiving community.

Requiring a death certificate that states the cause of death (or a specified alternative document) and requiring appropriate packaging of human remains mitigates the introduction and spread of communicable diseases into the United States with a minimum of recordkeeping and reporting as well as a minimum of interference with trade and travel. The death certificate will only be required for those seeking to import human remains that have not been embalmed or otherwise rendered noninfectious.

- At present, HHS/CDC has approval from OMB to collect certain information and impose recordkeeping requirements related to foreign quarantine responsibilities under OMB Control Number 0920–0134 (expiration 05/31/2019). HHS/CDC is proposing a non-substantive/nonmaterial change to:
- 42 CFR 71.55 Dead Bodies, 42 CFR 71.32(b)—Death certificates (No Form).
- 42 CFR 71.32 Statements or documentation of non-infectiousness (No Form).

[22] CDC (May 10, 2019) Notice of Temporary Suspension of Dogs Entering the United States From Egypt. 84 FR 20628. *https://www.federalregister.gov/documents/2019/05/10/2019-09654/notice-of-temporary-suspension-of-dogs-entering-the-united-states-from-egypt.*

Description of Respondents

Respondents to this data collection are individuals seeking to import human remains into the United States.

There is no burden to respondents other than the time taken to acquire a death certificate for the human remains being imported to the United States or to produce documentation stating that the human remains have been embalmed or otherwise rendered non-infectious. However, death certificates and embalming documentation are routinely produced by mortuary providers or hospitals after a death. DOS also provides a consular mortuary certificate that also commonly states the cause of death for an individual who dies abroad or, if the cause of death is not known, can reference whether the person died of a communicable disease. HHS/CDC does not anticipate significant additional administrative burden in acquiring these documents.

With data provided by CBP, CDC is updating the estimate of the number of imports of human remains that will require a death certificate from 20 to 150, and increasing by 1850 the estimate of the number of human remains that will require some statement or documentation of non-infectiousness. CDC believes this is a more accurate estimate of the volume of imported human remains imported into the United States, and not an increase in respondent burden. As stated above, both of these documents are routinely provided by mortuary services and do not represent an increase in respondent burden specifically for this proposed rulemaking

Additionally, as this NPRM proposes to clarify the requirements for importing human remains, HHS/CDC is also proposing to rename the provision. The associated information collections will clearly reference the title:

- 42 CFR 71.55 Importation of Human Remains—Death Certificate (No Form).
- 42 CFR 71.32, 71.55 Statements or documentation of non-infectiousness (No Form).

Table 5 below presents the estimate of annual burden (in hours) associated with the reporting requirement under this OMB control number, accounting for the proposed rule changes.

TABLE 5—ESTIMATED ANNUAL REPORTING BURDEN 0920–0134

Type of respondent	Regulatory provision or form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Importers	42 CFR 71.55 Importation of Human Remains—Death Certificate (No Form).	150	1	1	150
Importer	42 CFR 71.32, 71.55 Statements or documentation of non-infectiousness (No Form).	3,850	1	5/60	321

The estimates are based on experience to date with current recordkeeping and reporting requirements of 42 CFR 71.55 Dead Bodies—Death Certificate (No Form) and 42 CFR 71.32 Statements or documentation of non-infectiousness, are based on discussion with partners at DOS and DHS.

❨2) Application for Permit to Import Biological Agents and Vectors of Human Disease into the United States and Application for Permit to Import or Transport Live Bats (42 CFR 71.54) (OMB Control No. 0920–0199) No Change Requested—Center for Preparedness and Response, Centers for Disease Control and Prevention.

CDC/DSAT administers OMB Control No. 0920–0199 and does not propose any changes in information collection. Due to DSAT's experience with issuing CDC import permits, DSAT does not expect any additional burden from respondents because respondents understand that any material including human remains that is reasonably suspected of containing an infectious biological agent submits an application for CDC import permit.

On an annual basis, DSAT usually receives approximately 3 applications for importing human remains that are known to contain or reasonably suspected of containing an infectious biological agent. DSAT performs inspection of these requests to ensure that the facility has the appropriate biosafety conditions to receive these materials. DSAT plans to use current resources for processing any applications received for importing human remains that are known to contain or reasonably suspected of containing an infectious biological agent.

E. National Environmental Policy Act (NEPA)

HHS/CDC has determined that the proposed amendments to 42 CFR part 71 will not have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is needed.

F. E.O. 12988: Civil Justice Reform

HHS/CDC has reviewed this rule under Executive Order 12988 on Civil Justice Reform and determines that this NPRM meets the standard in the Executive Order.

G. E.O. 13132: Federalism

Under Executive Order 13132, if the rulemaking would limit or preempt State authorities, then a federalism analysis is required. The agency must consult with State and local officials to determine whether the rule would have a substantial direct effect on State or local Governments, as well as whether it would either preempt State law or impose a substantial direct cost of compliance on them.

HHS/CDC has determined that this NPRM will not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

H. Plain Language Act of 2010

Under 63 FR 31883 (June 10, 1998), Executive Departments and Agencies are required to use plain language in all proposed and final rules. HHS/CDC has attempted to use plain language in this rulemaking to make our intentions and rationale clear and requests input from the public in this regard.

List of Subjects in 42 CFR Part 71

Burial, Communicable diseases, Cremation, Death certificate, Entombment, Human remains, Importer, Infectious biological agent, Leak-proof container, Public health, Quarantinable communicable diseases.

For the reasons discussed in the preamble, we propose to amend 42 CFR part 71 as follows:

PART 71—FOREIGN QUARANTINE

■ 1. The authority citation for part 71 continues to read as follows:

Authority: Secs. 215 and 311 of Public Health Service (PHS) Act. as amended (42

U.S.C. 216, 243); secs. 361–369, PHS Act, as amended (42 U.S.C. 264–272).

■ 2. Amend § 71.50(b) by adding, in alphabetical order, the definitions ''Death certificate'', ''Human remains'', ''Importer'', and ''Leak-proof container'' to read as follows:

§ 71.50 Scope and definitions.

* * * * *

(b)* * *

* * * * *

Death certificate means an official government document that certifies that a death has occurred and provides identifying information about the deceased, including (at a minimum) name, age, and sex. The document must also certify the time, place, and cause of death (if known). If the official government document is not written in English, then it must be accompanied by an English language translation of the official government document, the authenticity of which has been attested to by a person licensed to perform acts in legal affairs in the country where the death occurred. In lieu of a death certificate, a copy of the Consular Mortuary Certificate and the Affidavit of Foreign Funeral Director and Transit Permit, shall together constitute acceptable identification of human remains.

* * * * *

Human remains means a deceased human body or any portion of a deceased human body, except:

(i) Clean, dry bones or bone fragments; human hair; teeth; fingernails or toenails; or

(ii) A deceased human body and portions thereof that have already been fully cremated prior to import; or

(iii) Human cells, tissues or cellular or tissue-based products intended for implantation, transplantation, infusion, or transfer into a human recipient.

Importer means any person importing or attempting to import an item regulated under this subpart.

* * * * *

Leak-proof container means a container that is puncture-resistant and sealed in such a manner as to contain all contents and prevent leakage of fluids during handling, storage, transport, or shipping, such as

(i) A double-layered plastic, puncture-resistant body bag (*i.e.,* two sealed body bags, one inside the other);

(ii) A casket with an interior lining certified by the manufacturer to be leak-proof and puncture-resistant; or

(iii) A sealed metal body-transfer case.

* * * * *

■ 3. Revise § 71.55 to read as follows:

§ 71.55 Importation of human remains.

(a) Human remains imported into the United States, or in transit within the United States and not intended for import, must be fully contained within a leak-proof container that is packaged and shipped in accordance with all applicable legal requirements.

(b) The provisions of § 71.54 shall apply to all imported human remains known to contain or reasonably suspected of containing an infectious biological agent.

(c) Unless accompanied by a permit issued under § 71.54, human remains imported into the United States must meet one of the following requirements:

(1) Human remains imported for burial, entombment, or cremation must:

(i) Be consigned directly to a licensed mortuary, cemetery, or crematory for immediate and final preparation prior to burial, entombment, or cremation; and

(ii) Unless embalmed, be accompanied by a death certificate or, if the death certificate is incomplete or missing, an importer certification statement confirming that the human remains are not known to contain or stating why the human remains are not reasonably suspected of containing an infectious biological agent.

(2) Human remains imported for medical examination or autopsy must:

(i) Be consigned directly to an entity authorized to perform such functions under the laws of the applicable jurisdiction prior to subsequent burial, entombment, or cremation; and

(ii) Unless embalmed, be accompanied by a death certificate or, if the death certificate is incomplete or missing, an importer certification statement confirming that the human remains are not known to contain or stating why the human remains are not reasonably suspected of containing an infectious biological agent.

(3) Human remains imported for any other purpose, unless embalmed, must be accompanied by an importer certification statement confirming that the human remains are not known to contain or stating why the human remains are not reasonably suspected of containing an infectious biological agent.

(d) The Director may suspend the importation of human remains under 42 CFR 71.63 if the Director designates the foreign country and determines that such an action is necessary to protect the public health.

Dated: October 31, 2019.

Alex M. Azar II,

Secretary, Department Of Health and Human Services.

[FR Doc. 2019–24943 Filed 11–22–19; 8:45 am]

BILLING CODE 4163–18–P