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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 71

[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: Final rule.

SUMMARY: The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), is issuing this Final Rule (FR) to amend two provisions within its Foreign Quarantine regulations to best protect the public health of the United States. The provisions in this Final Rule clarify various safeguards to prevent the importation and spread of communicable diseases affecting human health into the United States from threats posed by human remains.

DATES: This rule is effective [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Direct written comments regarding the Paperwork Reduction Act (PRA) items contained in this document by [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

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

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I. Public Participation

On November 25, 2019, HHS/CDC published a notice of proposed rulemaking (NPRM) (84 FR 64808) to amend 42 CFR part 71 (Foreign Quarantine). The public was invited to comment on these amendments. In the NPRM, HHS/CDC specifically requested public comment on the following:

- Proposed Definitions for "death certificate," "human remains," "importer," and "leak-proof container."
- Whether other valid documents should be accepted in lieu of a death certificate.
- The applicability of 42 CFR 71.63 to 42 CFR 71.55.
- The costs to importers to support inspections and respond to CDC questions.
- Repackaging costs or decomposition costs.

The public comment period for the proposed rule ended on January 24, 2020, and HHS/CDC received three comments from the public. A summary of those comments and responses to those comments are found at Section IV, below.

II. Background

A. 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 Secretary¹ 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. A detailed explanation of these legal authorities was provided in the NPRM published at 84 FR 64809.

B. Regulatory History

On November 25, 2019, HHS/CDC published a Notice of Proposed Rulemaking to update 42 CFR 71.50 and 42 CFR 71.55 within its Foreign Quarantine regulations to address the risk to public health from the importation of human remains into the United States. The provisions contained within the proposal were designed to enhance HHS/CDC's ability to prevent the importation and spread of communicable diseases

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 Fed. Reg. 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 Pub. L. No. 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 authority for carrying out the functions of the Surgeon General under 42 U.S.C. 264 and 265.

into the United States and interstate by clarifying for the public HHS/CDC's capabilities and current practices, while also making them more transparent.

III. Summary of the Final Rule

To best reflect current practice, HHS/CDC has renamed 42 CFR 71.55 "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." Also for added clarity, HHS/CDC has included 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."

Updated 42 CFR 71.55(a), now states that 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.

Section 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 § 71.55(c)(1)(i), to ensure that human remains imported for final resting enter only for the intended purpose, we have included a 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.

Under § 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.

Section 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 language addresses the other uses for human remains such as medical training or anatomical display.

Finally, under § 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.

As in the proposal, HHS/CDC notes that certain federal partners, such as the Department of Defense (DOD) and the Department of State (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 Final Rule 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. We note also that, under this Final Rule, 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.

Upon consideration of the public comments received, HHS/CDC did not make any changes to the language proposed to amend part 71 as set forth in the November 2019 NPRM (84 FR 64808). Therefore, this regulation is finalized as proposed.

IV. Overview of Public Comments to the 2019 NPRM

On November 25, 2019, HHS/CDC published a Notice of Proposed Rulemaking proposing to amend the current foreign quarantine regulations for the control of communicable diseases. The NPRM included a 60-day public comment period and during this time, HHS/CDC received three comments from the public.

All comments received were in support of this regulation. All three of the commenters expressed that this regulation is important for safeguarding public health. In addition, one commenter expressed that the updated regulation "represent[s] an appropriate response to complaints concerning public health" and "the updated definition and unambiguous re-codification of these provisions are simple enough for a (sic) someone lacking education in medicine to understand and can be adhered to by almost anyone." Furthermore, another commenter expressed that "... these new provisions would be a good idea to amend, as they make the

process of bringing remains to the United States safer [...] these additional safety nets are needed, especially when regarding public health.”

HHS/CDC thanks the commenters for their input on the proposed rule.

V. Alternatives Considered

As discussed in more detail above and analyzed in VI(A), HHS/CDC amends 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 addition to quantitatively analyzing the economic impact of providing additional clarity and safeguards to address the public health risk from importation of human remains relative to the status quo baseline, HHS/CDC also considered alternatives to this Final Rule. HHS/CDC considered alternatives that were both more and less burdensome than the amendments to 42 CFR 71.50 and 71.55 described in this Final Rule.

First, HHS/CDC considered whether a leak-proof container was necessary for importing human remains. If HHS/CDC did not specify leak-proof containers for

importation, such an alternative would be a potentially less burdensome requirement than transport of human remains in leak-proof containers. This alternative may potentially reduce the burden of airlines and importers. However, the reduced burden is hard to quantify because it is unclear whether importers or airlines would change their current practices if the less burdensome alternative was chosen. HHS/CDC does not believe this regulatory alternative would significantly change the current status quo baseline.

First, the reduced burden to airlines of this alternative would probably be minor. The current requirements of the four largest U.S. carriers to ship human remains are already consistent with the HHS/CDC's leak-proof container requirement. If HHS/CDC did not specify that human remains be imported in leak-proof containers, airlines may choose to maintain their existing requirements for transporting human remains internationally in leak-proof containers to avoid exposures to their employees. The usage of leak-proof containers may also be regulated under the U.S. Department of Labor's Occupational Safety and Health Administration's requirements (refer to 29 CFR 1910.1030) after entry through ports of entry.

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 (DOT) packaging requirements delineated in 49 CFR 173.199. These requirements are more burdensome than HHS/CDC's leak-proof container requirement.

Another alternative would be to require a more burdensome requirement, such as a hermetically sealed casket, to import all un-embalmed human remains. This alternative would increase importers' burdens compared to the Final Rule. The increased burden, however, is hard to quantify because of limited data. The cost of this alternative would be much more expensive than the cost associated with 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. For the purposes of this Final Rule, HHS/CDC will apply an established definition of embalming as the 1) reduction of microorganisms within the dead human body; 2) retarding of organic decomposition, and 3) restoring the deceased to a life-like appearance².

² The American Board of Funeral Services Education, course content, 2001, and (3) Mayer, RG. *Embalming, History, Theory, and Practice*, 5th edition. 2012: McGraw-Hill Medical; ISBN 978-0-07-174139-2

From a public health perspective, embalming of human remains is considered a mechanism to render the remains noninfectious so they no longer pose a risk of exposure to communicable diseases. For some diseases, such as Ebola virus disease, embalming may pose a public health risk to personnel performing the embalming process because of the very high risk of exposure to blood and other body fluids; for these diseases, embalming is not recommended.

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)³. The documentation requirements listed in 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.

³ 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.

A less burdensome alternative would be to also eliminate 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.⁴ 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 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

⁴ Refer to 7 FAM 256.

country. However, 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 Final Rule, 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 individuals 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, and did not receive any public comments on the cost or burden of producing such documentation. 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 in new 42 CFR 71.55(c), once finalized, for un-embalmed human remains.

A more burdensome 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 leak-proof 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 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 such as suspension of six genera of African rodents to prevent further importation of monkeypox virus during the 2003 monkeypox

outbreak. The order was later replaced by an interim Final Rule on November 3, 2003 (42 CFR 71.56 and 42 CFR 1240.63). 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.

VI. Required Regulatory Analyses

A. Executive Orders 12866 and 13563

Executive Orders 12866 "Regulatory Planning and Review," and 13563 "Improving Regulation and Regulatory 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 amends 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.")^{5,6} In some cases, importers have misrepresented the contents of their shipped packages containing human remains, and the shipped containers with human remains were subsequently 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

⁵ <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/>.

⁶ <https://www.reuters.com/investigates/special-report/usa-bodies-brokers/>

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 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. While CDC has published guidance on its website, it believes that further rulemaking is needed to address these concerns. Therefore, HHS/CDC is formally amending 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 a role in either the importation of human remains or the regulation of such imports.

The 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 Final Rule 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 (PHDs).

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, under 42 CFR 71.55(c)(1)(i) 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' exposures 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 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 burdensome hermetically sealed casket to the less burdensome leak-proof 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 eliminates 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 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 in 42 CFR 71.55(b) of when 42 CFR 71.54 should apply to transport of human remains. The requirements under 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.

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-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 the new 42 CFR 71.55, once effective, 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 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 42 CFR 71.55. The hourly wage rates for two employees based in Washington-Baltimore-Arlington, DC-MD-VA-WV-PA are \$62.23

(GS-14) and \$73.20 (GS-15).⁷ 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 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 ⁸	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	\$63.99	2	\$10,238

⁷U.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.

⁸U.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.

	GS-14, step 5 and GS-15, step 5 levels			
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 new 42 CFR 71.55(a), once effective. 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 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 publishing of this 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 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 Statistics⁹. The average Federal per diem for lodging, meals, and incidental expenses was estimated at \$158 per day for one day.¹⁰ Assuming that inspections occur on average (0.5 times per year, the annual cost would be estimated at \$1,518 per year.

In addition to CDC costs, importers would have to spend time to support the inspection and respond to CDC questions. HHS/CDC did not receive public comments 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

⁹ Bureau of Transportation Statistics. Average Domestic Airfares (Atlanta, 2018 Q4). <https://transtats.bts.gov/AIRFARES/> Accessed on June 19, 2019.

¹⁰ FederalPay.org 2018 Federal Per Diem Rates. (Average of 50 states). <https://www.federalpay.org/perdiem/2018> Accessed on June 19, 2019.

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)¹¹. 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 Final Rule.

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	Number of hours spent per	Average hourly wage	Overhead multiplier	Annual cost

¹¹ 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.

		year	inspec- tion	rate ¹²		
GS-12 (step 5)	0.33	0.5	20	\$41.85	2	\$276
GS-13 (step 5)	0.33	0.5	20	\$49.76	2	\$328
GS-14 (step 5)	0.33	0.5	20	\$58.80	2	\$388
Total						\$993
Travel cost	Airfare ¹³	\$367	Hotel, food, lodging ¹⁴	\$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.

¹² 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.

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.

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 required 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 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 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.¹⁵ If this amount of

¹⁵U.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.

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).¹⁶ 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

¹⁶U.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.

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 ¹⁷	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

¹⁷U.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.

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), 71.54, and 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, and did not receive any public comments on these costs. By reducing confusion, some of these costs may be averted when 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 Final Rule 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), 71.54 and 71.55. However, the inspection process itself should allow importers to fully understand their import requirements in regard to shipping containers, documentation, or permits.

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 42 CFR 71.55 are better understood.

Finally, the language in 42 CFR 71.55(d) indicating that 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 cross-referencing an the existing requirement in 42 CFR 71.63. 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.¹⁸ 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

HHS/CDC has analyzed the impacts of the Final Rule under the Regulatory Flexibility Act (5 U.S.C. 601-612). Unless we certify that the Final Rule is not expected to have a significant economic impact on a substantial

¹⁸ 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>

number of small entities, the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), requires agencies to analyze regulatory options that would minimize any significant economic impact of a rule on small entities. Based on our analysis as described above, we certify that this Final Rule will not have a significant economic impact on a substantial number of small entities within the meaning of the RFA.

This regulatory action is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This Final Rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in cost or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

D. The Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC)

has submitted the information collection requests titled Foreign Quarantine Regulations (42 CFR part 71) (OMB Control No. 0920-0134) 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) to the Office of Management and Budget (OMB) for review and approval. CDC previously published a Notice of Proposed Rulemaking on November 25, 2019 to obtain comments from the public and affected agencies. CDC received no comments related to the previous document. This document serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information,

including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this document to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of final rule publication.

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 Final Rule is updating one information collection: 0920-0134. CDC invited public comment on the burden to the public outlined in the NPRM and did not receive any comments

Information Collections.

(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 03/31/2022). 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)

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 rulemaking

Additionally, as this Final Rule clarifies the requirements for importing human remains, HHS/CDC is also renaming 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 rule changes.

Table 5. Estimated Annual Reporting Burden 0920-0134

Type of Respondent	Regulatory Provision or Form Name	No. of Respondents	No. 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)	3850	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 did not make 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 requires submission of 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. Executive Order 12866

This rule is not being treated as a significant regulatory action as defined by Executive Order 12866. As such, it has not been reviewed by the Office of Management and Budget (OMB).

F. National Environmental Policy Act (NEPA)

HHS/CDC has determined that the amendments to 42 CFR part 71 will not have a significant impact on the human environment.

G. Executive Order 12988: Civil Justice Reform

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

H. Executive Order 13132: Federalism

Under Executive Order 13132, a Federalism analysis is required if a rulemaking has Federalism implications, would limit or preempt State or local law, or impose substantial direct compliance costs on State or local governments. Under such circumstances, a Federal agency must consult with State and local officials. Federalism implications is defined as having substantial direct effects on State or local governments, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Under 42 U.S.C. 264(e), Federal public health regulations promulgated under that section do not preempt State or local public health regulations, except in the event of a conflict with the exercise of Federal authority.

Other than to restate this statutory provision, this rulemaking does not alter the relationship between the Federal Government and State/local governments as set forth in 42 U.S.C. 264. There are no provisions in these regulations that impose direct compliance costs on State and local governments. Therefore, HHS/CDC believes that the rule does not warrant additional consultation under Executive Order 13132.

I. The Plain Language Act of 2010

Under the Plain Language Act of 2010 (Pub. L. 111-274, October 13, 2010), Executive Departments and Agencies are required to use plain language in all proposed and Final Rules. Prior to publication, this Final Rule was reviewed by specialists in health communication and education to ensure the content and intention, as well as substance, were clear and accurate. HHS/CDC did not receive any public comment concerning plain language.

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 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 the 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, paragraph (b), by adding in alphabetical order definitions for "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 42 CFR 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 42 CFR 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: June 3, 2020.

Alex M. Azar II

Secretary, Department of Health and Human Services

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