

Based on current data from eHCTERS, we estimate there are 2,374 HCT/P current registrants and 157 new registrants, for a total of 2,531 respondents annually. Information

collection provisions that include reporting activities are identified in table 1. The estimated burden for each of the individual reporting activities was calculated based on the annual

number of submissions, averaged among respondents, and based on informal communications with industry.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

| 21 CFR part 1271; establish and maintain records | Number of recordkeepers | Number of records per recordkeeper ² | Total annual records | Average burden per recordkeeping ² | Total hours ³ |
|---|-------------------------|---|----------------------|---|--------------------------|
| 1271.47; Establishing SOPs | 157 | 1 | 157 | 48 | 7,536 |
| 1271.47; Updating SOPs | 2,374 | 1 | 2,374 | 24 | 56,976 |
| 1271 Subparts C & D: Establishing and maintaining records documenting methods used in, and the facilities and controls used for, the manufacture of HCT/Ps, including but not limited to all steps in recovery, donor screening, donor testing, processing, storage, labeling, packaging, and distribution. | 2,531 | 3,311.36 | 8,381,049 | 0.26 (~15 minutes) | 2,170,493 |
| Total | | | 8,383,580 | | 2,235,005 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Decimals rounded to the nearest hundredth.

³ Rounded to the nearest whole number.

To calculate burden associated with the establishment and maintenance of operating procedures in accordance with applicable CGTP requirements, we

assume twice the time is necessary for new establishments. Burden we attribute to recordkeeping activities associated with the remaining

provisions in part 1271 is assumed to be distributed among the individual elements and averaged among respondents.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

| 21 CFR part 1271—human cells, tissues, and cellular and tissue-based products; activity | Number of respondents | Number of disclosures per respondent ² | Total annual disclosures | Average burden per disclosure ² | Total hours |
|---|-----------------------|---|--------------------------|--|-------------|
| Disclosing information as required under applicable good manufacturing practices/CGTP provisions. | 1,611 | 4,984.75 | 8,030,435 | 0.30 (~18 minutes) | 2,389,226 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Decimals rounded to the nearest hundredth.

As part of the recordkeeping requirements, certain provisions in part 1271 require the disclosure of information to third parties, particularly as it pertains to the distribution of HCT/Ps. We estimate a proportion of the respondents to the information collection (1,611) will incur burden resulting from these disclosures and have therefore accounted for burden that may be attributable to these distinct activities.

Our estimated burden for the information collection reflects an overall reduction of 150,137 hours and 347,843 responses annually, which corresponds to a decrease in the number HCT/P establishments and a decrease in the number HCT/Ps distributed since our last evaluation.

Dated: July 3, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Solicitation of Nominations for Membership To Serve on the Advisory Committee on Organ Transplantation

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Request for nominations.

SUMMARY: HRSA is seeking nominations of qualified candidates to be considered for appointment as members of the Advisory Committee on Organ Transplantation (ACOT or Committee). ACOT provides advice and recommendations to the Secretary of HHS (Secretary) on proposed Organ Procurement and Transplantation Network policies and such other matters as the Secretary determines. The Secretary also may seek the advice of

the Committee on other proposed policies.

DATES: Written nominations for membership on the ACOT will be received on a continuous basis.

ADDRESSES: Nomination packages must be submitted to the Executive Secretary, ACOT, Healthcare Systems Bureau, HRSA, Room 08W67, 5600 Fishers Lane, Rockville, Maryland 20857, or via email to: ACOTHRSA@hrsa.gov.

FOR FURTHER INFORMATION CONTACT: Shelley Grant, Executive Secretary, ACOT, at (301) 443-8036 or email sgrant@hrsa.gov. A copy of the ACOT charter and list of current members may be obtained by accessing the ACOT website at <https://www.organdonor.gov/about-dot/acot.html>.

SUPPLEMENTARY INFORMATION: In accordance with the Amended Final Rule of the Organ Procurement and Transplantation Network (42 CFR part

121), ACOT was established pursuant to 42 U.S.C. 217a and, in accordance with Public Law 92–463, was first chartered on September 1, 2000. ACOT meets up to three times during the fiscal year.

Nominations: HRSA is requesting nominations for voting members to serve as Special Government Employees (SGEs) on ACOT. The Secretary appoints ACOT members with the expertise needed to fulfill the duties of the Advisory Committee. Nominees sought are individuals involved in organ procurement, organ transplantation (including, but not limited to, transplant candidates, recipients, living organ donors, and families of deceased organ donors), bioethics, and other medical specialties involved in organ transplantation and in the identification and referral of donors. Interested applicants may self-nominate or be nominated by another individual or organization.

Individuals selected for appointment to the Committee will be invited to serve for a term up to 3 years. Members appointed as SGEs receive a stipend and reimbursement for per diem and travel expenses incurred for attending ACOT meetings and/or conducting other business on behalf of ACOT, as authorized by 5 U.S.C. 5703 of the Federal Advisory Committee Act for persons employed intermittently in government service.

The following information must be included in the package of materials submitted for each individual being nominated for consideration: (1) A letter of nomination stating the name, affiliation, and contact information for the nominee, the basis for the nomination (*e.g.*, what specific attributes, perspectives, and/or skills does the individual possess that would benefit the workings of ACOT), and the nominee's field(s) of expertise; (2) a biographical sketch of the nominee; (3) the name, address, daytime telephone number, and email address at which the nominator can be contacted; and (4) a current copy of the nominee's curriculum vitae. Nomination packages may be submitted directly by the individual being nominated or by the person/organization recommending the candidate. HRSA requests that applicants who submitted a nomination or a self-nomination in the past please resubmit the required candidate forms.

HHS endeavors to ensure that the membership of ACOT is fairly balanced in terms of points of view represented and that individuals from a broad representation of geographic areas, gender, and ethnic and minority groups, as well as individuals with disabilities, are considered for membership.

Appointments shall be made without discrimination on the basis of age, ethnicity, gender, sexual orientation, or cultural, religious, or socioeconomic status.

Individuals who are selected to be considered for appointment will be required to provide detailed information regarding their financial holdings, consultancies, and research grants or contracts. Disclosure of this information is required for HRSA ethics officials to determine whether there is a conflict between the SGE's public duties as a member of ACOT and their private interests, including an appearance of a loss of impartiality as defined by federal laws and regulations, and to identify any required remedial action needed to address the potential conflict.

Authority: In accordance with 42 CFR 121.12, the Secretary established ACOT pursuant to 42 U.S.C. 217a. The Committee is governed by the Federal Advisory Committee Act (5 U.S.C. appendix 2), which sets forth standards for the formation and use of advisory committees.

Maria G. Button,

Director, Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Extension of Temporary Suspension of Dogs Entering the United States From Countries With a High Risk of Rabies

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

ACTION: Notice.

SUMMARY: In order to protect the United States against the potential reintroduction of the dog-maintained rabies virus variant (DMRVV) into the United States, the Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), announces an extension of the current temporary suspension of the importation into the United States of dogs from countries at high-risk for enzootic rabies (DMRVV high-risk countries). This suspension includes dogs that have been in any DMRVV high-risk countries during the previous six months.

DATES: The extension of the temporary suspension of the importation of dogs into the United States from DMRVV high-risk countries will be implemented

on August 1, 2023, when the current suspension expires, and will remain in effect through July 31, 2024.

FOR FURTHER INFORMATION CONTACT:

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. Telephone: 1–800–232–4636. For information regarding CDC regulations for the importation of dogs: Dr. Emily Pieracci, D.V.M., Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H16–4, Atlanta, GA 30329. Telephone: 1–800–232–4636.

SUPPLEMENTARY INFORMATION: CDC is extending, but not modifying, the terms of the current temporary suspension of the importation into the United States of dogs from countries at high-risk for enzootic rabies (DMRVV high-risk countries), including dogs that have been in any DMRVV high-risk countries during the previous six months. A suspension remains necessary to protect the public's health against the reintroduction of the dog-maintained rabies virus variant (DMRVV) into the United States. There is a continued threat posed by dogs from DMRVV high-risk countries which are unvaccinated or inadequately vaccinated against rabies. This continued threat is due to various factors, including: a high volume of dogs being imported into the United States contemporaneous with insufficient veterinary controls in DMRVV high-risk countries to prevent the export of inadequately vaccinated dogs, inadequate global veterinary supply chains for vaccines and related materials, and persistent workforce capacity shortages, particularly in DMRVV high-risk countries that export dogs to the United States. CDC anticipates that these factors are likely to continue over the course of the next 12 months. Considering these factors, CDC has determined that it is necessary to extend the temporary suspension through July 31, 2024, to ensure dogs imported into the United States do not pose a public health threat of reintroducing DMRVV into the United States.¹

¹ In consideration of both the anticipated needs for global rabies vaccine campaigns to return to pre-pandemic levels and to avoid disruption to importers' and the travel industry's operations, CDC has determined that a one-year extension of the temporary suspension is required to protect the public's health and is therefore in the public's interest. In the absence of a further extension of the temporary suspension or the adoption of an alternate framework to mitigate the importation of dogs infected with rabies, dog importation requirements would return to procedures that