

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>—Continued

Activity (21 CFR Part)	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours <sup>2</sup>
4.105(b) additional recordkeeping by device-led combination products .....	279	0.45	126	0.5	63

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.<sup>2</sup> Totals may not sum due to rounding.

New information technology applications have allowed us to more accurately calculate the number of registrants of medical device facilities that submit information electronically. Therefore, there is a 50 percent reduction in the number of respondents who will submit corrections and removals using the electronic process.

In addition, under OMB control number 0910-0834 ("Postmarketing Safety Reporting for Combination Products"), an additional 200 hours have been added to the annual reporting burden and an additional 63 hours have been added to the annual recordkeeping burden to comply with the PMSR requirements.

We have therefore revised the number of respondents to the information collection. This adjustment has resulted in a 1,293-hour decrease of the estimated burden.

Dated: August 14, 2020.

**Lauren K. Roth,**

Associate Commissioner for Policy.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2020-N-0008]

### Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Circulatory System Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

**DATES:** The meeting will take place virtually on October 7, 2020, from 9 a.m. Eastern Time to 6 p.m. Eastern Time.

**ADDRESSES:** Please note that due to the impact of the COVID-19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

**FOR FURTHER INFORMATION CONTACT:** Aden Asefa, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring, MD 20993-0002, [aden.asefa@fda.hhs.gov](mailto:aden.asefa@fda.hhs.gov), 301-796-0400, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

**SUPPLEMENTARY INFORMATION: Agenda:** The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On October 7, 2020, the committee will discuss, make recommendations, and vote on information regarding the premarket approval application (PMA) for the TransMedics Organ Care System (OCS)—Heart, by TransMedics, Inc. The proposed Indication for Use for the TransMedics OCS—Heart, as stated in the PMA, is as follows:

The TransMedics OCS Heart System is a portable *ex-vivo* organ perfusion and monitoring system indicated for the resuscitation, preservation, and assessment of donor hearts with one or more of the following characteristics for transplantation into a potential recipient

in a near-physiologic, normothermic, and beating state:

- Expected cross-clamp or ischemic time ≥4 hours due to donor or recipient characteristics (e.g., donor-recipient geographical distance, expected recipient surgical time)
  - Donor Age ≥55 years
  - Donors with history cardiac arrest and downtime ≥20 minutes
  - Donor history of alcohol use
  - Donor LV Ejection Fraction ≤50 percent but ≥40 percent
  - Donor history of Left Ventricular Hypertrophy (septal or posterior wall thickness of >12 and ≤16 millimeters)
- FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material and the link to the online teleconference meeting room will be available at <https://www.fda.gov/advisory-committees/circulatory-system-devices-panel/2020-meeting-materials-circulatory-system-devices-panel>. Select the link for the 2020 Meeting Materials. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 1, 2020. Oral presentations from the public will be scheduled on October 7, 2020, between approximately 1 p.m. Eastern Time and 2 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**). The notification should include a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed

participants, and an indication of the approximate time requested to make their presentation on or before September 23, 2020. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 25, 2020.

For press inquiries, please contact the Office of Media Affairs at [fdaoma@fda.hhs.gov](mailto:fdaoma@fda.hhs.gov) or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Ann Marie Williams at [Annmarie.Williams@fda.hhs.gov](mailto:Annmarie.Williams@fda.hhs.gov) or 301-796-5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 14, 2020.

**Lauren K. Roth,**  
Associate Commissioner for Policy.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Proposed Updates to the Bright Futures Periodicity Schedule as Part of the HRSA-Supported Preventive Services Guidelines for Infants, Children, and Adolescents

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

**ACTION:** Notice.

**SUMMARY:** The Periodicity Schedule of the Bright Futures Recommendations for Pediatric Preventive Health Care (“Bright Futures Periodicity Schedule”), as part of the HRSA-supported preventive service guidelines for infants, children, and adolescents, is

maintained in part through a national cooperative agreement, the Bright Futures Pediatric Implementation Program.

**DATES:** Members of the public are invited to provide written comments no later than September 21, 2020. All comments received on or before this date will be reviewed and considered by the Bright Futures Periodicity Schedule Workgroup and provided for further consideration by HRSA in determining the recommended updates that it will support.

**ADDRESSES:** Members of the public interested in providing comments can do so by accessing the public comment web page at: <https://mchb.hrsa.gov/maternal-child-health-topics/child-health/bright-futures.html>.

**FOR FURTHER INFORMATION CONTACT:** Bethany Miller, HRSA, Maternal and Child Health Bureau, email: [BMiller@hrsa.gov](mailto:BMiller@hrsa.gov), telephone: (301) 945-5156.

**SUPPLEMENTARY INFORMATION:** The Bright Futures Program has been funded as a cooperative agreement by HRSA since 1990. A primary focus of this program is for the funding recipient to maintain and update the Bright Futures Guidelines for Health Supervision of Infants, Children and Adolescents, a set of materials and tools for providing quality preventive care screenings and well-child visits. One component of these tools is the Bright Futures Periodicity Schedule, a chart that identifies the recommended screenings, assessments, physical examinations, and procedures to be delivered within preventive checkups at each age milestone. Over the program’s existence, the Bright Futures Periodicity Schedule has become the accepted schedule within the United States for preventive health services through the course of a child’s development.

Under the Public Health Service Act, non-grandfathered group health plans and health insurance issuers must include coverage, without cost sharing, for certain preventive services, for plan years (in the individual market, policy years) that begin on or after the date that is one year after the date the recommendation or guideline is issued. These include preventive health services provided for in the Bright Futures Periodicity Schedule as part of the HRSA-supported Preventive Services Guidelines for Infants, Children, and Adolescents. A panel of pediatric primary care experts convened to review the latest evidence and recommends updating the Bright Futures Periodicity Schedule to include screening all individuals ages 18 and

older at least once for hepatitis C virus infection. This proposed update aligns with the United States Preventive Services Task Force’s recommendation that all adults ages 18 to 79 be screened at least once for hepatitis C virus infection.

The American Academy of Pediatrics, which has been the HRSA cooperative agreement recipient for this program since 2007, maintains the Periodicity Schedule. Under HRSA’s cooperative agreement with the American Academy of Pediatrics, the Bright Futures Program is required to administer a process for developing and regularly recommending, as needed, updates to the Bright Futures Periodicity Schedule. As described in the Notice of Funding Opportunity for the Bright Futures Program (HRSA-18-078), the consideration of potential updates is expected to be “a comprehensive, objective, and transparent review of available evidence that incorporates opportunity for public comment.”

**Thomas J. Engels,**

*Administrator.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

**[OMB No. 0906-xxxx—New]**

#### Agency Information Collection

**Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Enhancing Linkage of Sexually Transmitted Infection and Human Immunodeficiency Virus Surveillance Data in the Ryan White HIV/AIDS Program Evaluation**

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

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR should be received no later than October 19, 2020.