

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN¹—Continued

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
610.47(a)(3)	1,734	11.7630	20,397	.17 (10 min.)	3,467
610.47(b)(3)	4,961	0.4132	2,050	1	2,050
630.40(a) ³	578	742.214	429,000	.08 (5 min.)	34,320
630.40(a) ⁴	81	50.00	4,050	1.5	6,075
630.40(d)(1)	53	11.83	627	1	627
Total					57,701

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

² Five percent of establishments that fall under CLIA that transfuse blood and components and FDA-registered blood establishments (0.05 × 4,961 + 2,303 = 363).

³ Notification of donors determined not to be eligible for donation based on failure to satisfy eligibility criteria.

⁴ Notification of donors deferred based on reactive test results for evidence of infection due to relevant transfusion-transmitted infections.

The burden for this information collection has changed since the last OMB approval. Because of a slight decrease in the number of blood establishments during the last 3 years, FDA has decreased our recordkeeping and third party disclosure burden estimates.

Dated: January 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Tick-Borne Disease Working Group

AGENCY: Office of HIV/AIDS and Infectious Disease Policy, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) announces the third meeting of the Tick-Borne Disease Working Group (Working Group) on February 12, 2018, from 12:00 p.m. to 4:00 p.m., Eastern Time. For this third meeting, the Working Group will focus on mapping out the work of the six Subcommittee Meeting Working Groups that were established on December 12, 2017. These subcommittees were established to assist the Working Group with the development of the report to Congress and the HHS Secretary as required by the 21st Century Cures Act. The subcommittees are:

1. Disease Vectors, Surveillance and Prevention (includes epidemiology of tick-borne diseases);
2. Pathogenesis, Transmission, and Treatment;

3. Testing and Diagnostics (including laboratory-based diagnoses and clinical-diagnoses);

4. Access to Care Services and Support to Patients;

5. Vaccine and Therapeutics; and

6. Other Tick-Borne Diseases and Co-infections.

DATES: February 12, 2018, from 12:00 p.m. to 4:00 p.m., Eastern Time.

ADDRESSES: This will be a virtual meeting that is held via webcast. Members of the public may attend the meeting via webcast and instructions for attending this virtual meeting will be posted one week prior to the meeting at: <https://www.hhs.gov/ash/advisory-committees/tickbornedisease/index.html>.

FOR FURTHER INFORMATION CONTACT: James Berger, Office of HIV/AIDS and Infectious Disease Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services; via email at tickbornedisease@hhs.gov or by phone at 202–795–7697.

SUPPLEMENTARY INFORMATION: At this meeting, the Working Group will also hear about one or more examples of other efforts that have been successfully undertaken to define a national or statewide approach to preventing, monitoring, diagnosing, and treating people with tick-borne diseases. In addition, federal resources, within and outside of HHS, that may be of use to the subcommittees as they do their work, such as the Department of Health and Human Services Internal Working Group on Lyme and Other Tick-Borne Diseases, will be presented.

The Working Group invites public comment on issues related to the Working Group’s charge. Comments may be provided over the phone during the meeting or in writing. Persons who wish to provide comments by phone should review directions at <https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/index.html>

before submitting a request via email at tickbornedisease@hhs.gov on or before February 7, 2018. Phone comments will be limited to three minutes each to accommodate as many speakers as possible. A total of 30 minutes will be allocated to public comments. If more requests are received than can be accommodated, speakers will be randomly selected. The nature of the comments will not be considered in making this selection. Public comments may also be provided in writing. Individuals who would like to provide written comment should review directions at <https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/index.html> before sending their comments to tickbornedisease@hhs.gov on or before February 7, 2018.

Background and Authority: The Tick-Borne Disease Working Group was established on August 10, 2017, in accordance with section 2062 of the 21st Century Cures Act, and the Federal Advisory Committee Act, 5 U.S.C. App., as amended, to provide expertise and review all HHS efforts related to tick-borne diseases to help ensure interagency coordination and minimize overlap, examine research priorities, and identify and address unmet needs. In addition, the Working Group will report to the Secretary and Congress on their findings and any recommendations for the federal response to tick-borne disease prevention, treatment and research, and addressing gaps in those areas.

Dated: January 17, 2018.

James Berger,

Alternate Designated Federal Officer, Office of HIV/AIDS and Infectious Disease Policy, Tick-Borne Disease Working Group.

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