

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

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours ²	Total operating and maintenance costs
Information regarding compromised quality; AB ⁴ —900.12(j)(1).	20	1	20	320	6,400	646
Patient notification of serious risk—900.12(j)(2)	5	1	5	100	500	20,878
Reconsideration of accreditation—900.15(c)	5	1	5	2	10
Notification of requirement to correct major deficiencies—900.24(a).	0.4	1	0.4	200	80	73
Notification of loss of approval; major deficiencies—900.24(a)(2).	0.15	1	0.15	100	15	27
Notification of probationary status—900.24(b)(1)	0.3	1	0.3	200	60	55
Notification of loss of approval; minor deficiencies—900.24(b)(3).	0.15	1	0.15	100	15	27
Total	3,691,842	26,141,344

¹ There are no capital costs associated with the collection of information.
² Total hours have been rounded.
³ Refers to the facility component of the burden for this requirement.
⁴ Refers to the AB component of the burden for this requirement.
⁵ Refers to the situation where a patient specifically does not want to receive the lay summary of her exam.

FDA has adjusted the number of respondents for § 900.3(c) “AB renewal of approval” to one. This adjustment resulted in a 14-hour increase to the hour-burden estimate. Additionally, we updated the capital costs and operating and maintenance costs by adjusting them for inflation since the last update to those estimates. This adjustment resulted in a \$1,893,071 increase to the estimated capital and operating and maintenance costs (\$24,410,106 previously; \$26,303,177 current extension request).

Dated: August 12, 2019.

Lowell J. Schiller,
Principal 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 the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the Tick-Borne Disease Working Group (TBDWG) will hold a meeting. The meeting will be open to the public. For this meeting, the Working Group will receive updates from the eight subcommittees formed at the June 4, 2019, meeting and continue to focus on plans to develop the next report to the

HHS Secretary and Congress on federal tick-borne activities and research, taking into consideration the 2018 report. The 2020 report will address a wide range of federal activities and research related to tick-borne diseases, such as, surveillance, prevention, diagnosis, diagnostics, and treatment; identify gaps in tick-borne disease research; and provide recommendations to the HHS Secretary regarding changes or improvements to such activities and research. In developing the report, the TBDWG will solicit stakeholder input.

DATES: The meeting will be online via webcast and will be held on September 12, 2019, from 8:30 a.m. to 5 p.m. ET (times are tentative and subject to change). The confirmed times and agenda items for the meeting will be posted on the website for the TBDWG at <https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/2019-9-12/index.html> when this information becomes available.

ADDRESSES: Members of the public may also attend the meeting via webcast. Instructions for attending the virtual meeting will be posted one week prior to the meeting at <https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/2019-9-12/index.html>.

FOR FURTHER INFORMATION CONTACT: James Berger, Designated Federal Officer for the TBDWG; Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services, Mary E Switzer Building, 330 C Street SW, Suite L100, Washington, DC 20024. Email: tickbornedisease@hhs.gov; Phone: 202-795-7697.

SUPPLEMENTARY INFORMATION: The public will have an opportunity to present their views to the TBDWG

during the meeting’s public comment session or by submitting their views in writing. Comments should be pertinent to the meeting discussion. Persons who wish to provide verbal or written public comment should review instructions at <https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/2019-9-12/index.html> and respond by midnight Wednesday, September 4, 2019, ET. Verbal comments will be limited to three minutes each to accommodate as many speakers as possible during the 30 minute session. Written public comments will be accessible to the TBDWG members and public on the TBDWG web page prior to the meeting.

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 federal efforts related to tick-borne diseases to help ensure interagency coordination and minimize overlap, examine research priorities, and identify and address unmet needs. The TBDWG is required to submit a report to the HHS Secretary and Congress on their findings and any recommendations for the federal response to tick-borne disease every two years.

Dated: August 6, 2019.

James Berger,
Designated Federal Officer, Tick-Borne Disease Working Group, Senior Advisor for Blood and Tissue Policy, Office of Infectious Disease and HIV/AIDS Policy.

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