

protocols in fiscal year (FY) 2017, under the regulations cited previously in this document. FDA estimates that approximately 75 manufacturers submitted protocols under § 610.2 and 2 manufacturers submitted protocols under the regulation (§ 660.6) for the other specific product. FDA received no submissions under §§ 660.36 or 660.46; however, FDA is using the estimate of one protocol submission under each regulation in the event that protocols are submitted in the future.

The estimated total annual responses are based on FDA's final actions completed in FY 2017 for the various submission requirements of samples and protocols for the licensed biological products. The average burden per response is based on information provided by industry. The burden estimates provided by industry ranged from 1 to 5.5 hours. Under § 610.2, the hours per response are based on the average of these estimates and rounded to 3 hours. Under the remaining

regulations, the average burden per response is based on the higher end of the estimate (rounded to 5 or 6 hours) since more information is generally required to be submitted in the other protocols than under § 610.2.

In the **Federal Register** of May 11, 2018, (83 FR 22081), we published a notice soliciting public comment of the information collection. No comments were received.

We therefore estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR section/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
610.2—Requests for Samples and Protocols; Official Release	75	86.267	6,470	3	19,410
660.6(b)—Protocols	2	3.5	7	5	35
660.36(a)(2) and (b)—Samples and Protocols	1	1	1	6	6
660.46(b)—Protocols	1	1	1	5	5
Total					19,456

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

Our estimated burden for the information collection reflects an overall increase of 764 hours and a corresponding increase of 262 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: August 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-0438]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health

and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before September 19, 2018.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395-5806.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795-7714. When submitting comments or requesting information, please include the document identifier 0990-New-30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection

techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Office of Adolescent Health Teen Pregnancy Prevention, FY 2015–2020 Performance Measure Collection.

Type of Collection: Extension.

OMB No. 0990-0438.

Abstract: The Office of Adolescent Health (OAH), U.S. Department of Health and Human Services (HHS), is requesting renewal by OMB of the existing information collection request for performance measures collection from the TPP grant recipients. Performance measure data collection is a requirement of TPP grants; the extension will allow for the completion of data collection from cohort 2. The collection will provide OAH with performance data to inform planning decisions; identify technical assistance needs for grantees; facilitate grantees' continuous quality improvement in program implementation; and provide HHS, Congress, OMB, and the general public with information about the individuals who participate in TPP-funded activities.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Grant Recipient—Dissemination Form	84	2	15/60	42
Grant Recipient—Partnerships Form	84	2	15/60	42

ESTIMATED ANNUALIZED BURDEN TABLE—Continued

Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Grant Recipient—Facilitator Training Form	84	2	15/60	42
Grant Recipient—Healthcare Linkages Form	84	2	15/60	42
Grant Recipient: Participant Reach Form	84	2	168/60	470
Grant Recipient: Dosage Form	84	2	102/60	286
Grant Recipient Fidelity Form	84	2	102/60	286
Grant Recipient: Cost Form	84	1	30/60	42
Total	1252

Terry Clark,

Office of the Secretary, Asst Paperwork Reduction Act Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Advisory Committee on Children and Disasters Public Teleconference

AGENCY: Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services is hereby giving notice that the National Advisory Committee on Children and Disasters (NACCD) will hold a public teleconference on September 11, 2018.

DATES: The NACCD Public Teleconference is September 11, 2018, from 2:00 p.m. to 3:00 p.m. Eastern Daylight Time (EDT).

ADDRESSES: We encourage members of the public to attend the public meetings. To register, send an email to naccd@hhs.gov with “NACCD Registration” in the subject line. Submit your comments to naccd@hhs.gov or via the NACCD Contact Form located at <https://www.phe.gov/Preparedness/legal/boards/naccd/Pages/contact.aspx>. For additional information, visit the NACCD website located at <https://www.phe.gov/naccd>.

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), and Section 2811A of the Public Health Service (PHS) Act (42 U.S.C. 300hh–10a), as added by Section 103 of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5), the HHS

Secretary, in consultation with the Secretary of the U.S. Department of Homeland Security, established the NACCD. The purpose of the NACCD is to provide advice and consultation to the HHS Secretary with respect to the medical and public health needs of children in relation to disasters.

Background: The September 11, 2018, public teleconference of the NACCD is dedicated to the presentation, deliberation, and vote on the Pediatric Disaster Training Work Group (PDTWG) and Identifying Metrics of Baseline Vulnerability (IMBV) reports. Established under the NACCD in 2017, the PDTWG met several times over the past year to evaluate progress since the 2011 National Center for Disaster Medicine and Public Health consensus report and to develop recommendations to further improve pediatric training to ensure the safety and health of children in disasters. Separately, in 2018, the ASPR identified metrics of baseline community vulnerability as a topic he would like the NACCD to address and provide recommendations. On June 28, 2018, the NACCD met publically and in-person to develop metrics via a facilitated discussion. Takeaways from this discussion served as the basis for the IMBV report. We will post modifications to the agenda on the NACCD meeting website, which is located at <https://www.phe.gov/naccd>.

Availability of Materials: We will post all teleconference materials prior to the teleconference on September 11, 2018, at the website located at <https://www.phe.gov/naccd>.

Procedures for Providing Public Input: Members of the public may attend the public teleconference via a toll-free call-in phone number, which is available on the NACCD website at <https://www.phe.gov/naccd>.

We encourage members of the public to provide written comments that are relevant to the NACCD public teleconference prior to September 11, 2018. Send written comments by email to naccd@hhs.gov with “NACCD Public

Comment” in the subject line. The NACCD Chair will respond to comments received by September 10, 2018, during the public teleconference.

Dated: August 13, 2018.

Robert P. Kadlec,

Assistant Secretary for Preparedness and Response.

[FR Doc. 2018–17901 Filed 8–17–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Advisory Committee on Children and Disasters and National Biodefense Science Board Public Teleconference

AGENCY: Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services is hereby giving notice that the National Advisory Committee on Children and Disasters (NACCD) and National Biodefense Science Board (NBSB), also known as the National Preparedness and Response Science Board (NPRSB), will hold a joint public teleconference on September 12, 2018.

DATES: The NBSB and NACCD Joint Public Teleconference is September 12, 2018, from 2:00 p.m. to 3:00 p.m. Eastern Daylight Time (EDT).

ADDRESSES: We encourage members of the public to attend the public meetings. To register, send an email to naccd@hhs.gov with “NACCD Registration” in the subject line, or to nprsb@hhs.gov with “NBSB Registration” in the subject line. Submit your comments to naccd@hhs.gov, nprsb@hhs.gov, the NBSB Contact Form located at <https://www.phe.gov/Preparedness/legal/boards/nprsb/Pages/RFNBSBComments.aspx>, or the NACCD Contact Form