

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN¹

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
606.145(c)	4,961	0.2822	1,400	0.02	28
606.170(a)	² 363	12	4,356	0.5 (30 min.) ..	2,178
610.40(c)(1)(ii)	2,303	0.0595	137	0.08 (5 min.) ..	11
610.40(h)(2)(ii)(C) and (h)(2)(ii)(D)	15	12	180	0.20 (12 min.) ..	36
610.40(h)(2)(vi)	2,303	3.28	7,554	0.08 (5 min.) ..	604
610.42(a)	1	1	1	1	1
610.46(a)(1)(ii)(B)	1,734	5.2266	9,063	0.17 (10 min.) ..	1,541
610.46(a)(3)	1,734	5.2266	9,063	0.17 (10 min.) ..	1,541
610.46(b)(3)	4,961	0.3538	1,755	1	1,755
610.47(a)(1)(ii)(B)	1,734	11.7630	20,397	0.17 (10 min.) ..	3,467
610.47(a)(3)	1,734	11.7630	20,397	0.17 (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	0.08 (5 min.) ..	34,320
630.40(a) ⁴	81	50	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: April 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Training in Primary Care Medicine and Dentistry

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

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD) will hold a public meeting.

DATES: Thursday, May 3, 2018, from 8:30 a.m. to 5:00 p.m. and Friday, May 4, 2018, from 8:30 a.m. to 2:00 p.m. ET.

ADDRESSES: The address for the meeting is 5600 Fishers Lane, Rockville,

Maryland 20857, Room 5E29. The conference call-in number: 1-800-857-9729 and Passcode: 1318150. The webinar link is <https://hrsa.connectsolutions.com/actpcmd>.

FOR FURTHER INFORMATION CONTACT:

Anyone requesting information regarding the ACTPCMD should contact Dr. Kennita R. Carter, Designated Federal Official (DFO), Division of Medicine and Dentistry, Bureau of Health Workforce, HRSA, in one of three ways: (1) Send a request to the following address: Dr. Kennita R. Carter, DFO, Division of Medicine and Dentistry, HRSA, 5600 Fishers Lane, Room 15N-116, Rockville, MD 20857; (2) call 301-945-3505; or (3) send an email to KCarter@hrsa.gov.

SUPPLEMENTARY INFORMATION:

ACTPCMD provides advice and recommendations to the Secretary of the Department of Health and Human Services on policy, program development, and other matters of significance concerning the activities under section 747 of Title VII of the Public Health Service Act (PHSA). ACTPCMD prepares an annual report describing the activities of the Committee, including findings and recommendations made by the Committee concerning the activities under section 747, as well as training programs in oral health and dentistry. The annual report is submitted to the Secretary and ranking members of the Senate Committee on Health, Education, Labor and Pensions, and the House of Representatives Committee on Energy

and Commerce. The Committee also develops, publishes, and implements performance measures and guidelines for longitudinal evaluations of programs authorized under Title VII, Part C, of the PHSA, and recommends appropriation levels for programs under this Part.

During the May 3-4, 2018, meeting, ACTPCMD will review the impact of the Title VII, Section 747 and oral health training programs, and make recommendations on funding and appropriation levels. In addition, the Committee will identify its strategic priorities for the coming year, and discuss issues related to pending Committee reports on the integration of behavioral health into primary care and oral health training, and clinical trainee and faculty well-being and resilience. Information about ACTPCMD and the agenda for this meeting is located on the ACTPCMD website at <https://www.hrsa.gov/advisory-committees/primarycare-dentist/index.html>. Please note that agenda items are subject to change as priorities dictate.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to make oral comments or provide written comments to the ACTPCMD should be sent to Dr. Carter, DFO, using the contact information above at least three business days prior to the meeting.

The building at 5600 Fishers Lane, Rockville, MD 20857, requires a security screening on entry. To facilitate access to the building, please contact Dr. Carter at the contact information listed above. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify Dr. Carter at the address and phone number listed above at least 10 days prior to the meeting.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018-07910 Filed 4-16-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Full Committee Meeting.

Date and Times: Tuesday, May 15, 2018: 9:00 a.m.–5:00 p.m. (EDT), Wednesday, May 16, 2018: 8:30 a.m.–2:45 p.m. (EDT).

Place: U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue SW, Rm. 705A, Washington, DC 20201.

Status: Open.

Purpose: At the May 15–16, 2018 meeting, the Committee will hear presentations, hold discussions on several health data policy topics and work on activities outlined in the NCVHS 2018 workplan. Anticipated action items during this meeting include a letter to the Secretary and a summary report of the hearing held September 2017 on the topic of the national vital records and vital statistics systems. In addition, a letter to the Secretary regarding the Committee's recommendations resulting from the March Standards Subcommittee Hearing on NCPDP Updates will be considered for approval. The Office of the National Coordinator (ONC) will give an update and the Committee will discuss its collaboration with ONC and its advisory committee HITAC. Subcommittee activities for discussion include the CIO Forum to be held in May and the Predictability Roadmap as part of the Standards Subcommittee's project to identify possible approaches to improve predictability and improvements in the

adoption and processes related to updating standards and operating rules for electronic administrative transactions (e.g., claims, eligibility, electronic funds transfer). The agenda and plans for the July meeting examining health terminology & vocabulary development, maintenance, and dissemination processes will be discussed together with a draft environmental scan report. The Committee will continue development of its Health Information Privacy & Security Beyond HIPAA project focusing on clinical registries as a use case. The Committee also will discuss any recent developments resulting from the initial wave of the Medicare Card Project roll out.

The times and topics are subject to change. Please refer to the posted agenda for any updates.

Contact Persons for More Information:

Substantive program information may be obtained from Rebecca Hines, MHS, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Hyattsville, Maryland 20782, telephone (301) 458-4715. Summaries of meetings and a roster of Committee members are available on the home page of the NCVHS website: www.ncvhs.hhs.gov, where further information including an agenda and instructions to access the audio broadcast of the meetings will also be posted.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (770) 488-3210 as soon as possible.

Dated: April 10, 2018.

Laina Bush,

Deputy Assistant Secretary for Planning and Evaluation, Office of the Assistant Secretary for Planning and Evaluation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Standards Subcommittee Meeting.

Date and Times: Thursday, May 17, 2018: 9:00 a.m.–4:30 p.m. (EDT).

Place: Bureau of Labor Statistics, Janet Norwood Conference and Training Center, Postal Square Building, 2 Massachusetts Ave NE, Room G440, Washington, DC 20212 (Entrance on First Street across from Union Station).

Status: Open. There will be a public comment period during the final 15 minutes of the subcommittee meeting.

Purpose: Health Insurance Portability and Accountability Act (HIPAA) legislation from 1996, as amended,¹ directed the Secretary of HHS to publish regulations adopting administrative standards, code sets and identifiers to support the exchange of electronic health information between covered entities. The standards are for retail pharmacy and medical transactions.

NCVHS is working on the development of a standards update and adoption roadmap (the predictability roadmap), in collaboration with industry stakeholders and the Standards Development Organizations (SDOs). The purpose of this roadmap is to improve the predictability of the update and adoption process of the standards and operating rules. It is the intent of the collaboration effort to identify the barriers to updating and adopting standards and make constructive, actionable recommendations for all parties, so that covered entities can more effectively conduct their business, operational and technical strategic planning.

NCVHS held a visioning exercise with the Standards Development Organizations (SDOs) in August 2017, and developed a set of draft action steps and recommendations. The next step towards finalizing recommendations for the Secretary, is to convene a group of Chief Information Officers (CIOs) who work with the standards and operating rules as end users, with health care leaders from various fields of health care technology. The CIOs and health care innovators will exchange information based on their experience and expertise. The CIOs will discuss their changing business and technology needs specifically as these pertain to the standards that have been adopted under HIPAA such as claims, eligibility, referrals and authorizations. Some individuals will share their experience using the standards day to day, and to increase efficiencies in their organizations. Other participants will share their experience implementing or seeing innovative technology being used for the exchange of electronic health care information.

¹ Along with Section 1104(c) of the Patient Protection and Affordable Care Act (ACA) of 2010.