

FDA estimates the annual reporting burden for the draft guidance as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Rare pediatric disease designation request	51	1	51	75	3,825
Rare pediatric disease priority review voucher request	20	1	20	40	800
Notification of intent to use a voucher	3	1	3	8	24
Transfer notification	2	1	2	8	16
Post-approval report	2	1	2	20	40
Total					4,705

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

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <https://www.regulations.gov>.

Dated: July 24, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-16262 Filed 7-29-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Request for Information: Ensuring Patient Access and Effective Drug Enforcement

AGENCY: Office of the Assistant Secretary for Planning and Evaluation (ASPE), HHS.

ACTION: Request for Information.

SUMMARY: This Request for Information (RFI) seeks comment on ensuring legitimate access to controlled substances, including opioids, while also preventing diversion and abuse, as well as how federal, state, local, and tribal entities can collaborate to address these issues.

DATES: Comments must be received at one of the addresses provided below, no later than 5 p.m. on August 29, 2019.

ADDRESSES: Written comments can be provided by email, fax or U.S. mail.

Email: EPAEDEAreport@hhs.gov.

Fax: (202) 690-5882.

Mail: U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation,

Office of Science and Data Policy, Attn: EPAEDEA Report Feedback, 200 Independence Avenue SW, Room 434E, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Office of the Assistant Secretary for Planning and Evaluation, 202-690-7100.

SUPPLEMENTARY INFORMATION:

I. Background

Section 3 of the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 (EPAEDEA), Public Law 114-145, called for the Department of Health and Human Services, acting through the Commissioner of Food and Drugs, the Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the Agency for Healthcare Research and Quality, and the Director of the Centers for Disease Control and Prevention, and in coordination with the Administrator of the Drug Enforcement Administration and in consultation with the Secretary of Defense and the Secretary of Veterans Affairs, to submit a report to Congress that identifies:

- Obstacles to legitimate patient access to controlled substances;
- issues with diversion of controlled substances;
- how collaboration between Federal, State, local, and tribal law enforcement agencies and the pharmaceutical industry can benefit patients and prevent diversion and abuse of controlled substances;
- the availability of medical education, training opportunities, and comprehensive clinical guidance for pain management and opioid prescribing, and any gaps that should be addressed;
- beneficial enhancements to State prescription drug monitoring programs, including enhancements to require comprehensive prescriber input and to

expand access to the programs for appropriate authorized users;

- steps to improve reporting requirements so that the public and Congress have more information regarding prescription opioids, such as the volume and formulation of prescription opioids prescribed annually, the dispensing of such prescription opioids, and outliers and trends within large data sets.

II. Solicitation of Comments

EPAEDEA requires that the report incorporate feedback and recommendations from the following: (1) Patient groups; (2) pharmacies; (3) drug manufacturers; (4) common or contract carriers and warehousemen; (5) hospitals, physicians, and other health care providers; (6) State attorneys general; (7) Federal, State, local, and tribal law enforcement agencies; (8) health insurance providers and entities that provide pharmacy benefit management services on behalf of a health insurance provider; (9) wholesale drug distributors; (10) veterinarians; (11) professional medical societies and boards; (12) State and local public health authorities; and (13) health services research organizations.

This RFI is seeking comment from these stakeholders on the aforementioned issue areas to be covered by the report.

III. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble.

Dated: July 16, 2019.

Brenda Destro,

Deputy Assistant Secretary for Planning and Evaluation (HSP).

[FR Doc. 2019–16145 Filed 7–29–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Environmental Health Sciences Review Committee; Environmental Health Sciences; P30 Core Centers.

Date: August 14–15, 2019.

Time: 8:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Imperial Hotel Raleigh-Durham Airport at Research Triangle Park, 4700 Emperor Blvd., Durham, NC 27703.

Contact Person: Linda K. Bass, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute Environmental Health Sciences, P.O. Box 12233, MD EC–30, Research Triangle Park, NC 27709, 984–287–3236, bass@niehs.nih.gov.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel; Environmental Health Sciences P30 Core Centers.

Date: August 15, 2019.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Imperial Hotel Raleigh-Durham Airport at Research Triangle Park, 4700 Emperor Blvd., Durham, NC 27703.

Contact Person: Varsha Shukla, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute Environmental Health Sciences, Keystone Building, Room 3094, Research Triangle Park, NC 27709, 984–287–3288, Varsha.shukla@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from

Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: July 24, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–16066 Filed 7–29–19; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

[Docket No. CISA–2019–0010]

Notice of the President’s National Infrastructure Advisory Council Meeting

AGENCY: Cybersecurity and Infrastructure Security Agency, DHS.

ACTION: Announcement of meeting; request for comments.

SUMMARY: The Cybersecurity and Infrastructure Security Agency (CISA) announces a public meeting of the President’s National Infrastructure Advisory Council (NIAC). To facilitate public participation, CISA invites public comments on the agenda items and any associated briefing materials to be considered by the council at the meeting.

DATES:

Meeting Registration: Individual registration to attend the meeting in person is required and must be received no later than 5:00 p.m. EST on August 7, 2019.

Speaker Registration: Individuals may register to speak during the meeting’s public comment period must be received no later than 5:00 p.m. EST on August 7, 2019.

Written Comments: Written comments must be received no later than 12:00 p.m. EST on August 14, 2019.

NIAC Meeting: The meeting will be held on Thursday, August 15, 2019 from 2:00 p.m.–4:00 p.m. EST.

ADDRESSES: The NIAC meeting will be held at The United States Naval Academy, Laboon Center, 566 Brownson Rd., Annapolis, MD 21402.

Comments: Written comments may be submitted on the issues to be considered by the NIAC as described in the **SUPPLEMENTARY INFORMATION** section below and any briefing materials for the meeting. Any briefing materials that will

be presented at the meeting will be made publicly available on Friday, August 2, 2019 at the following website: <https://www.dhs.gov/national-infrastructure-advisory-council>.

Comments identified by docket number “CISA–2019–0010” may be submitted by any of the following methods:

- *Federal eRulemaking Portal:* www.regulations.gov. Follow the instructions for submitting written comments.

- *Email:* NIAC@hq.dhs.gov. Include docket number CISA–2019–0010 in the subject line of the message.

Instructions: All submissions received must include the agency name and docket number for this notice. All written comments received will be posted without alteration at www.regulations.gov, including any personal information provided. For detailed instructions on sending comments and additional information on participating in the upcoming NIAC/NSTAC meeting, see the “Public Participation” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket and comments received by the NIAC, go to www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Ginger K. Norris, 202–441–5885, ginger.norris@hq.dhs.gov.

SUPPLEMENTARY INFORMATION: The NIAC is established under Section 10 of E.O. 13231 issued on October 16, 2001. Notice of this meeting is given under the Federal Advisory Committee Act (FACA), 5 U.S.C. Appendix (Pub. L. 92–463). The NIAC shall provide the President, through the Secretary of Homeland Security, with advice on the security and resilience of the Nation’s critical infrastructure sectors.

The NIAC will meet in an open meeting on August 15, 2019 to discuss the following agenda items with DHS leadership.

Agenda

- I. Call to Order and Opening Remarks
 - II. Panel Discussion With Critical Infrastructure Experts on Cross Sector Interdependencies
 - III. New Business
 - IV. Public Comment
 - V. Closing Remarks
 - VI. Adjournment
- Public Participation Meeting Registration Information

Due to additional access requirements and limited seating, requests to attend in person will be accepted and processed in the order in which they are received. Individuals may register to