



This document is scheduled to be published in the Federal Register on 07/30/2019 and available online at <https://federalregister.gov/d/2019-16145>, and on [govinfo.gov](https://www.govinfo.gov)

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 5p.m. on **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

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

E-mail: 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)

BILLING CODE: 4150-15

[FR Doc. 2019-16145 Filed: 7/29/2019 8:45 am; Publication Date: 7/30/2019]