

Why GAO Did This Study

The DEA administers and enforces the CSA as it pertains to ensuring the availability of controlled substances, including certain prescription drugs, for legitimate use while limiting their availability for abuse and diversion. The CSA requires those handling controlled substances to register with DEA.

GAO was asked to review registrants' and others' interactions with DEA. This report examines (1) to what extent registrants interact with DEA about their CSA responsibilities, and registrants' perspectives on those interactions, (2) how state agencies and national associations interact with DEA, and their perspectives on those interactions, and (3) stakeholders' perspectives on how DEA enforcement actions have affected prescription drug abuse and diversion and access to those drugs for legitimate needs. GAO administered nationally representative web-based surveys to DEA-registered distributors, individual pharmacies, chain pharmacy corporate offices, and practitioners. GAO also interviewed officials from DEA, 26 national associations and other nonprofits, and 16 government agencies in four states representing varying geographic regions and overdose death rates.

What GAO Recommends

GAO recommends that DEA take three actions to improve communication with and guidance for registrants about their CSA roles and responsibilities. DEA described actions that it planned to take to implement GAO's recommendations; however, GAO identified additional actions DEA should take to fully implement the recommendations.

View [GAO-15-471](#). For more information, contact Linda Kohn at (202) 512-7114 or kohnl@gao.gov or George Scott at (202) 512-8777 or scottg@gao.gov.

PRESCRIPTION DRUGS

More DEA Information about Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access

What GAO Found

GAO's four nationally representative surveys of Drug Enforcement Administration (DEA) registrants showed that these registrants vary in the extent of their interaction with DEA related to their roles and responsibilities for preventing prescription drug abuse and diversion under the Controlled Substances Act (CSA). Specifically, GAO found that distributors and chain pharmacy corporate offices interacted with DEA more often than individual pharmacies or health care practitioners. The surveys also showed that many registrants are not aware of various DEA resources. For example, GAO estimates that 70 percent of practitioners are not aware of DEA's Practitioner's Manual. Of those registrants that have interacted with DEA, most were generally satisfied with those interactions. For example, 92 percent of distributors that communicated with DEA field office staff found them "very" or "moderately" helpful. However, some distributors, individual pharmacies, and chain pharmacy corporate offices want improved guidance from, and additional communication with, DEA about their CSA roles and responsibilities. For example, 36 of 55 distributors commented that more communication or information from, or interactions with, DEA would be helpful. DEA officials indicated that they do not believe there is a need for more registrant guidance or communication. Federal internal control standards call for adequate communication with stakeholders. Without more registrant awareness of DEA resources and adequate guidance and communication from DEA, registrants may not fully understand or meet their CSA roles and responsibilities.

Officials GAO interviewed from 14 of 16 state government agencies and 24 of 26 national associations said that they interact with DEA through various methods. Thirteen of 14 state agencies and 10 of 17 national associations that commented about their satisfaction with DEA interactions said that they were generally satisfied; however, some associations wanted improved DEA communication. Because the additional communication that four associations want relates to their members' CSA roles and responsibilities, improved DEA communication with and guidance for registrants may address some of the associations' concerns.

Among those offering a perspective, between 31 and 38 percent of registrants GAO surveyed and 13 of 17 state agencies and national associations GAO interviewed believe that DEA enforcement actions have helped decrease prescription drug abuse and diversion. GAO's survey results also showed that over half of DEA registrants have changed certain business practices as a result of DEA enforcement actions or the business climate these actions may have created. For example, GAO estimates that over half of distributors placed stricter limits on the quantities of controlled substances that their customers (e.g., pharmacies) could order, and that most of these distributors (84 percent) were influenced to a "great" or "moderate extent" by DEA's enforcement actions. Many individual pharmacies (52 of 84) and chain pharmacy corporate offices (18 of 29) reported that these stricter limits have limited, to a "great" or "moderate extent," their ability to supply drugs to those with legitimate needs. While DEA officials said they generally did not believe that enforcement actions have negatively affected access, better communication and guidance from DEA could help registrants make business decisions that balance ensuring access for patients with legitimate needs with controlling abuse and diversion.