

**OFFICE OF THE CENTER DIRECTOR**

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**Forecasting Schedule I and II Substance and Drug Needs**

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**PURPOSE**

- This MAPP establishes specific responsibilities in the Center for Drug Evaluation and Research (CDER) for offices reporting usage data applied in forecasting Schedule I and Schedule II substance and drug needs to the Drug Enforcement Administration (DEA).
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**BACKGROUND**

- The Department of Health and Human Services (DHHS) is responsible for providing the DEA with annual estimates of the amounts of specific Schedule I and Schedule II substances and drugs that will be needed for medical and scientific use. The DEA relies on these estimates to establish annual manufacturing quotas for the substances and drugs (Controlled Substances Act – CSA and the Public Health Services Act - PHSA). The Controlled Substance Staff (CSS) in CDER is responsible for ensuring that DEA's manufacturing quotas for Schedule I and Schedule II substances and drugs are sufficient to meet medical and scientific needs. CSS gathers quantitative information from offices in CDER and from the Drug Shortage Committee for all Schedule I and II substances and drugs under current INDs, NDAs, ANDAs, supplemental NDAs (sNDAs), or for Schedule II drugs that are discontinued or in short supply. CSS provides this information to the DEA.
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**REFERENCES**

- Controlled Substances Act (CSA) of 1970, as amended (primarily 21 U.S.C. 812 and 826)
  - 21 Code of Federal Regulations (CFR) parts 5 and 1300
  - Public Health Service Act (PHSA), Title 42 U.S.C. 242 (a)
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**DEFINITIONS**

- **Schedule I Substances and Drugs:** Drugs with high abuse potential and no accepted medical use in the United States. Examples of Schedule I drugs are heroin, marijuana, lysergic acid diethylamide (LSD), and methaqualone. A complete list of current Schedule I substances and drugs maintained by the DEA can be found on the Internet at [http://www.deadiversion.usdoj.gov/21cfr/cfr/1308/1308\\_11.htm](http://www.deadiversion.usdoj.gov/21cfr/cfr/1308/1308_11.htm).
  - **Schedule II Drugs:** Drugs with high abuse potential and an accepted medical use in the United States. Examples of Schedule II drugs include morphine, methadone, oxycodone, hydrocodone, amphetamine, methylphenidate and pentobarbital. A complete list of current Schedule II drugs maintained by the DEA can be found on the Internet at [http://www.deadiversion.usdoj.gov/21cfr/cfr/1308/1308\\_12.htm](http://www.deadiversion.usdoj.gov/21cfr/cfr/1308/1308_12.htm).
  - **Quotas:** The quantities of Schedule I and Schedule II substances and drugs that DEA allows pharmaceutical companies to manufacture each year, as permitted by the CSA.
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**RESPONSIBILITIES****1. The Controlled Substances Staff will:**

- Gather information from FDA's Center for Veterinary Medicine (CVM), CDER offices, and other government agencies regarding INDs, NDAs, ANDAs, sNDAs, discontinued products, and product shortages for Schedule I and II substances and drugs.
- Request data on the use of Schedule II drugs in Narcotic Treatment Programs from the Substance Abuse and Mental Health Services Administration (SAMHSA).
- Compile these data and prepare usage estimates for Schedule I and Schedule II substances and drugs for the coming year.
- Analyze usage, shortage, significant regulatory actions, and other data received from FDA and other government sources.
- Monitor and communicate current developments in the areas of drug shortages, approvals, manufacturing, and regulatory actions that may affect availability, thus requiring quota adjustments.
- Prepare an annual report summarizing usage and shortage data, prescribing trends and estimates of future needs for Schedule I and II substances and drugs, and forward the annual report to the DEA.

**2. The Office of New Drugs and Office of Generic Drugs will:**

- Notify CSS of the designated individual assigned to respond to a CSS request for information.
- Respond to CSS requests for information on INDs, NDAs, ANDAs, sNDAs, discontinued products, and product shortages for Schedule I and Schedule II substances and drugs received for the reporting year.

3. **The Office of Biostatistics will:**

- Obtain and analyze pharmaceutical sales and marketing data provided by the Office of Drug Safety (ODS) for Schedule II drugs and precursors to establish trends and forecast future needs.
  - Provide data to CSS in tabular form and work with CSS in generating the final report.
  - Develop and refine statistical models for the annual forecast.
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**EFFECTIVE DATE**

This MAPP is effective upon date of publication.