



# DEA compliance starts with solid recordkeeping

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In sports, records are meant to be broken. In the business and legal world, records are meant to be requested. Government investigators and lawyers love records, and when required records are incomplete or unavailable, penalties often ensue.

The DEA's Diversion Control Division works to ensure controlled substances are not misused or illegally distributed and requires dental and medical professionals, including oral and maxillofacial surgeons, to maintain accurate records of these substances.

Professionals with experience in regulatory compliance understand the importance of listening when regulators speak. Staying on top of regulatory requirements is paramount, especially since agencies like the DEA periodically update their standards.

What will the DEA look for when it inspects an OMS office? Apart from required patient dispensing and distribution records, the DEA may look for the following documentation:

## ■ List of employees with controlled substance access

– This includes employee authorization forms, employee questionnaires and controlled substance authorized user logs. Registrants should conduct background checks on any employee who will have access to controlled substances to confirm they have not been convicted of a felony related to controlled substances or had an application for DEA registration denied, revoked or surrendered for cause.

Also, registrants should maintain a list of employees who will have access to controlled substances. The number of individuals who have access to controlled substances should be kept to the minimum necessary.

■ **Receiving records** – DEA Form 222 is required for each distribution or procurement of a Schedule II controlled substance. Copies of Form 222 – as well as all linked records for an order such as invoices, purchase orders and packing slips – must be maintained for two years.



■ **Power of attorney** – If registrants want an employee to be able to order controlled substances using Form 222, they must formally designate the employee as a power of attorney.

■ **Initial and biennial inventories** – Registrants must maintain complete and accurate inventories of all stocks and forms of controlled substances in their possession. For each of the Schedule II and Schedule III-IV controlled substances, the following inventories must be maintained:

- **Initial inventory** – The actual physical count of all controlled substances held on the date registrants first engage in administering controlled substances.
- **Biennial inventory** – The actual physical count of all controlled substances held, at least every two years from the date of the initial inventory. Logs to note usage or spillage of controlled substances will help oversight of current inventories.

■ **Records of destruction** – If registrants dispose of controlled substances using a reverse distributor, they must collect and retain a DEA Form 222 for Schedule II controlled substances and record of the dates and manner of disposal for Schedule III-IV controlled substances. If registrants dispose of controlled substances by a means other than a reverse distributor, they must list the controlled substances being disposed of on a DEA Form 41.

■ **Theft/loss reports** – In the event of a theft or significant loss of controlled substances, registrants must notify the local DEA Diversion Field Office in writing within one

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business day of the theft/loss and complete a DEA Form 106.

All of these records must be complete and accurate, readily retrievable and kept for two years.

DEA Diversion Control Division staff outlined several common issues often identified during registration inspections during its April presentation – Preparing for a DEA Inspection: What to expect and how to better prevent diversion. These issues include:

- Inadequate accountability for controlled substances.
- Improper execution of DEA Form 222.
- Missing or outdated powers of attorney, including lack of revocations.
- Absence of initial and biennial inventories or incomplete/inaccurate records.
- Improper handling of controlled substance take-backs.
- Failure to notify the DEA of drug theft or loss.

Recordkeeping is top-of-mind for the DEA and U.S. Attorneys' Offices, and deficiencies in recordkeeping can lead to financial and other penalties. For example, a Pennsylvania-based oral and maxillofacial surgeon was fined \$120,000 in late 2024 for multiple violations, including:

- Failing to use the required DEA Form 222 for each distribution of a Schedule II controlled substance.
- Failing to maintain complete and accurate records of controlled substances dispensed by him at both of his registered locations.

- Failing to maintain biennial inventories at both of his registered locations.

In the press release pertaining to this matter, former U.S. Attorney Gerard M. Karam advised, "Practitioners who register with DEA in order to prescribe and dispense medications that fall under the Controlled Substances Act have an obligation to prescribe appropriately and keep careful records and inventories. ... Not fulfilling those obligations makes it difficult or even impossible to be sure those potentially dangerous medications are being dispensed and handled appropriately and are not being diverted."

Compliance with DEA recordkeeping requirements is not optional; it is essential to safe and lawful practice. ■

*Dental Office Compliance of New England, LLC (DOC4NE) assists provider clients with guidance on record retention, regulation compliance and best practices. Visit [DOC4NE.com](http://DOC4NE.com) or call 781-471-0915.*



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