

# Report on Medicare Compliance Volume 32, Number 44. December 11, 2023

## Tool for Auditing Compliance With the Controlled Substances Act (CSA)

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By Nina Youngstrom

UNC Health in North Carolina has developed a compliance guidebook to help its off-campus clinics understand CSA requirements and self-audit them, said Patrick Kennedy, executive system director of hospital compliance at UNC Health (see story, p. 1). Here are a few of the pages from the binder. Contact Kennedy at [patrick.kennedy@unchealth.unc.edu](mailto:patrick.kennedy@unchealth.unc.edu).

### Summary of record requirements

Record Requirements	Forms	Notes
Every three years	<p>DEA license</p> <ul style="list-style-type: none"><li>• <b>DEA Form 224:</b> New clinic applications</li><li>• <b>DEA Form 224a:</b> Clinic renewal application</li></ul>	Should be posted on wall. Cost: Tax exempt for UNC clinics.
Biennial	CS inventory	After the initial inventory, registrant should take a new inventory of all controlled substance stocks on hand at least every two years. (May be taken on any date within two years of the previous biennial date.)

Annual	DHHS registration <ul style="list-style-type: none"> <li>DHHS <b>Form 224-D</b>: New clinic with no previous DHHS license <i>or</i></li> <li>DHHS <b>Form 226-D</b>: Clinic with previous DHHS license re-registering</li> </ul>	<p>Recommend to start renewal process two months in advance.</p> <p>Should be posted on wall.</p> <p>Cost: changes each year.</p>
	DEA <b>Form 222</b>	Stored in secure, locked location with limited access.
Daily	Invoices of purchases <ul style="list-style-type: none"> <li>CII</li> <li>CIII - CV</li> </ul>	Must be kept by registrant and available for at least three years from date of invoice for inspection.
	Invoices of sales to reverse distributors <ul style="list-style-type: none"> <li>CII</li> <li>CIII - CV</li> </ul>	Must be kept by registrant and available for at least three years from date of invoice for inspection.
	Power of attorney forms <ul style="list-style-type: none"> <li>Permissions</li> <li>Revocations</li> </ul>	Must be executed by the officer of the corporation (e.g., president) who signed the most recent application for DEA registration or re-registration and expires when POA is revoked by the person who signed the most recent application.
	CS inventory <ul style="list-style-type: none"> <li>Initial license approval</li> <li>License transfers</li> <li>Biennial inventories</li> </ul>	Should be completed on the date the inventory is taken and should be maintained in written, typewritten, or printed form at the registered location.

	<div>Reporting loss or theft</div> <div><ul style="list-style-type: none"><li>• DEA <b>Form 106</b> filing</li><li>• Discrepancies</li><li>• Unreconciled discrepancies and required police report</li></ul></div>	<div>DEA <b>Form 106</b> must be completed and submitted within one business day of discovery of the theft or loss.</div>
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Notes

- Unless noted otherwise, all required records concerning controlled substances must be maintained for at least three years for inspection and copying by duly authorized DEA officials.
- Inventories and records of CII medications must be stored separately from CIII–CV medications.
- Additionally, purchase records, received invoices and restock reports should be reconciled for each order by the registrant for diversion prevention.

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