

DEA Controlled Substances Audit Checklist

This checklist is used by the pharmacist-in-charge to prepare for a DEA Controlled Substance Audit.

1	<p>Does the person/pharmacy possess a current DEA registration? (21 CFR 1301)</p> <ul style="list-style-type: none"> • Specify expiration date of registration. • Note what schedules of controlled substances are covered under registration (e.g., CI, CII, CIII, CIV, CV). 	Yes	No
2	<p>Is the DEA registration specifically for the location that is being audited (e.g., does registration address match audit pharmacy license address)? (21 CFR 1301)</p> <p>a. If the DEA registration is not for the audit address, note what coincident activity is being performed at the audit site that is covered under another registration (e.g., analysis coincident to manufacturing [on a contiguous campus]) as defined in Part 1301.13(e).</p>	Yes	No
	b. If not (any of the above), is this site an office as defined in Part 1301.12(3)?	Yes	No
	c. Is the current registration for the audit site kept on-site?	Yes	No
	d. If the current registration for the audit site is not kept on-site, is there a letter to DEA requesting a central recordkeeping site?	Yes	No
3	Does the current DEA registrant sign the re-registration application?	Yes	No
4	Is there a current state pharmacy license on-site?	Yes	No
5	<p>Have criminal background checks been performed on all employees (W2/1099)?</p> <ul style="list-style-type: none"> • Employees who have a felony conviction with a “controlled substance” may work in a pharmacy. 	Yes	No
6	<p>Does the pharmacy have current powers-of-attorney on file for CSOS/DEA-222s? (21 CFR 1305.05)</p> <ul style="list-style-type: none"> • Compliance Portal®: DEA; Item #7c-iii, Power-of-Authority for DEA Forms 222 and Electronic Orders. 	Yes	No
7	<p>Are hard copy DEA 222s annotated with date received, quantity received and initialed? NOTE: The person initialing must have a power-of-attorney as described in Item #6.</p>	Yes	No
8	Are wholesale invoices attached to hard copy DEA 222s and readily available for DEA inspectors?	Yes	No
9	<p>Does the signer of the current application for registration execute the Powers-of-Authority? (21 CFR 1305.05)</p> <ul style="list-style-type: none"> • Compliance Binder “A”, Letters of Designation Tab. 	Yes	No
10	Does the pharmacy have CSOS Subscriber Agreement(s) on file? [21 CFR 1311.60(c)]	Yes	No
11	Is the CSOS certificate holder ensuring that no one else uses his/her password? (21 CFR 1311.30)	Yes	No
12	Are there any compounds on the premises and/or activities being performed that are not supported by the current registration?	Yes	No
13	Is the DEA biennial inventory on file? [21 CFR 1304.11(c)]	Yes	No
14	Are beginning of business (BOB) or close of business (COB) indicated? [21 CFR 1304.11(a)]	Yes	No
15	Is biennial inventory and all other inventories separated into Schedule II and Schedule III-V inventories? [21 CFR 1304.04(h)(1)+(h)(3)]	Yes	No
16	Are the quantities and date received annotated on Schedule II CSOS receipts and/or within pharmacy software? [21 CFR 1305.22(g)]	Yes	No
17	Are DEA 222 forms readily retrievable and ship quantity and date filled in for all for returns? [21 CFR 1305.13(b)(c)(d)+1305.17(b)(c)]	Yes	No

18	Are invoices for Schedule II readily retrievable (filed w/DEA 222 [recommended] or separately)? [21 CFR 1304.04(h)(1)]	Yes	No
19	Are Schedule III-V invoices separately filed with dates and quantity received? [21 CFR 13.04.04(h)(3)+1304.21(d)]	Yes	No
20	Are Schedule II prescriptions readily retrievable (separately filed)? [21 CFR 1304.04(h)(2)]	Yes	No
21	Are Schedule III-V prescriptions readily retrievable (separately filed)? [21 CFR 1304.04(h)(4)]	Yes	No
22	Is RPh familiar with procedures for theft and loss investigation and reporting? [21 CFR 1301.76(b)] <ul style="list-style-type: none"> Compliance Portal®: DEA; Item #6, DEA Report of Theft or Loss of Controlled Substance. 	Yes	No
23	Has pharmacy conducted CMEA training and printed certificate from DEA website? (21 CFR 1314.35, 1314.40, 1314.42) <ul style="list-style-type: none"> Compliance Portal®: DEA; Item #2b & 2c, Pseudoephedrine Training Log and Pseudoephedrine Training Certificate. 	Yes	No