

481—553.2(124,124B) General requirements.

553.2(1) Federal regulations. Registrants will comply with applicable federal laws and regulations relating to controlled substances, scheduled listed chemical products, and listed chemicals. 21 CFR Chapter 2 as amended on September 19, 2023, is incorporated herein by reference.

553.2(2) Records.

a. Retention. All records relating to controlled and precursor substances will be maintained at the registered or permitted location for at least two years from the last date of the record or entry to the record.

b. Accessibility. Electronic records will be capable of producing a hard-copy printout of transactions or entries for any specific date or range of dates requested. All records will be available for inspection and copying by the board or its authorized agent.

c. Storage. Original records more than 12 months old may be maintained in a secure remote storage area unless such remote storage is prohibited by federal law or regulation. Records maintained in remote storage locations will be retrievable within three business days of a request by the board or its authorized agent.

d. Receipt. In addition to the elements found in 21 CFR §1304.21 and 21 CFR §1304.22, each record of the receipt of controlled substances, including the receipt of complementary packages, will include the signature of the individual responsible for receiving the substances.

e. Dispensing. In addition to the elements found in Iowa Code section 124.306 and 21 CFR §1304.22, each registrant will maintain a record of controlled substances dispensed to a patient or research subject that includes:

- (1) The name and NDC number, strength, dosage form, and quantity of the substance dispensed.
- (2) The name of the prescriber, unless dispensed by the prescriber.
- (3) The unique identification of each technician, pharmacist, pharmacist-intern, prescriber, or prescriber's agent involved in dispensing.
- (4) The serial number or unique identification number of the prescription.

553.2(3) Inspections. Pursuant to Iowa Code section 124.302(5), the board may inspect the premises of a registrant, and the inspection may:

a. Be conducted at any time during the registrant's normal operating hours without advance notification to the registrant.

b. Include the review of any record relating to the registered activity.

[ARC 9339C, IAB 6/11/25, effective 7/16/25; see Delay note at end of chapter]