

**481—553.11(124) Dispensing scheduled listed chemical products without a prescription.** Pursuant to 21 U.S.C. §830 as amended on October 17, 2000, 21 CFR Part 1314, and Iowa Code section 124.212A, registrants will record the retail sales of scheduled listed chemical products. If the real-time electronic pseudoephedrine tracking system (PTS) is unavailable for use, the purchase will be recorded in an alternate format and submitted to the PTS in accordance with subrule 553.11(3).

**553.11(1) *Age restriction.*** Sales of scheduled listed chemical products are limited to persons aged 18 and older.

**553.11(2) *Reporting elements.*** In addition to the identified elements in 21 U.S.C. §830, 21 CFR Part 1314, and Iowa Code section 124.212A, the following information will be recorded:

- a. The purchaser's current government-issued photo identification number.
- b. The total milligrams of the scheduled listed chemical contained in the product.
- c. The name or unique identification of the individual who approved the sale.
- d. If applicable, the reason that a PTS recommendation to deny the transaction was overridden.

**553.11(3) *Alternate record format.*** If needed, an alternate record will be maintained using one of the following options:

- a. A hard-copy record.
- b. A record in the pharmacy's electronic prescription dispensing system that is capable of producing a hard-copy printout of the record.
- c. A record in an electronic data collection system that captures each of the required data elements and that is capable of producing a hard-copy printout of the record.

**553.11(4) *Delayed submission to the PTS.*** Sales of scheduled listed chemical products that are documented in an alternate record due to the inaccessibility of the PTS will be submitted to the PTS within 72 hours of the PTS being accessible, and such record will identify that it is a delayed entry.

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