§ 1314.20

(c) Written reports of losses must be filed within 15 days after the regulated person becomes aware of the circumstances of the event.

(d) A report submitted under this section must include a description of the circumstances of the loss (in-transit, theft from premises, etc.).

(e) A suggested format for the report is provided below:

<table>
<thead>
<tr>
<th>Regulated Person</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registration number (if applicable)</td>
</tr>
<tr>
<td>Name</td>
</tr>
<tr>
<td>Business address</td>
</tr>
<tr>
<td>City</td>
</tr>
<tr>
<td>State</td>
</tr>
<tr>
<td>Zip</td>
</tr>
<tr>
<td>Business phone</td>
</tr>
<tr>
<td>Date of loss</td>
</tr>
<tr>
<td>Type of loss</td>
</tr>
<tr>
<td>Description of circumstances</td>
</tr>
</tbody>
</table>

Subpart B—Sales by Regulated Sellers

§ 1314.20 Restrictions on sales quantity.

(a) Without regard to the number of transactions, a regulated seller (including a mobile retail vendor) may not in a single calendar day sell any purchaser more than 3.6 grams of ephedrine base, 3.6 grams of pseudoephedrine base, or 3.6 grams of phenylpropanolamine base in scheduled listed chemical products.

(b) A mobile retail vendor may not in any 30-day period sell an individual purchaser more than 7.5 grams of ephedrine base, 7.5 grams of pseudoephedrine base, or 7.5 grams of phenylpropanolamine base in scheduled listed chemical products.

§ 1314.25 Requirements for retail transactions.

(a) Each regulated seller must ensure that sales of a scheduled listed chemical product at retail are made in accordance with this section and § 1314.20.

(b) The regulated seller must place the product so that customers do not have direct access to the product before the sale is made (in this paragraph referred to as “behind-the-counter” placement). For purposes of this paragraph, a behind-the-counter placement of a product includes circumstances in which the product is stored in a locked cabinet that is located in an area of the facility where customers do have direct access. Mobile retail vendors must place the product in a locked cabinet.

(c) The regulated seller must deliver the product directly into the custody of the purchaser.

§ 1314.30 Recordkeeping for retail transactions.

(a) Except for purchase by an individual of a single sales package containing not more than 60 milligrams of pseudoephedrine, the regulated seller must maintain, in accordance with criteria issued by the Administrator, a written or electronic list of each scheduled listed chemical product sale that identifies the products by name, the quantity sold, the names and addresses of the purchasers, and the dates and times of the sales (referred to as the “logbook”).

(b) The regulated seller must not sell a scheduled listed chemical product at retail unless the sale is made in accordance with the following:

1. The purchaser presents an identification card that provides a photograph and is issued by a State or the Federal Government, or a document that, with respect to identification, is considered acceptable for purposes of 21 CFR 274a.2(b)(1)(v)(A) and 274a.2(b)(1)(v)(B).

2. The purchaser signs the logbook as follows:

   (i) For written logbooks, enters in the logbook his name, address, and the date and time of the sale.

   (ii) For electronic logbooks, provides a signature using one of the following means:

      (A) Signing a device presented by the seller that captures signatures in an electronic format. The device must display the warning notice in paragraph (d) of this section. Any device used must preserve each signature in a manner that clearly links that signature to the other electronically captured logbook information relating to the prospective purchaser providing that signature.

      (B) Signing a bound paper book.

   (I) The bound paper book must include, for such purchaser, either:

      (i) A printed sticker affixed to the bound paper book at the time of sale
that either displays the name of each product sold, the quantity sold, the name and address of the purchaser, and the date and time of the sale, or a unique identifier which can be linked to that electronic information, or

(ii) A unique identifier that can be linked to that information and that is written into the book by the seller at the time of sale.

(2) The purchaser must sign adjacent to the printed sticker or written unique identifier related to that sale. The bound paper book must display the warning notice in paragraph (d) of this section.

(C) Signing a printed document that includes, for the purchaser, the name of each product sold, the quantity sold, the name and address of the purchaser, and the date and time of the sale. The document must be printed by the seller at the time of the sale. The document must contain a clearly identified signature line for a purchaser to sign. The printed document must display the warning notice in paragraph (d) of this section. Each signed document must be inserted into a binder or other secure means of document storage immediately after the purchaser signs the document.

(3) The regulated seller must enter in the logbook the name of the product and the quantity sold. Examples of methods of recording the quantity sold include the weight of the product per package and number of packages of each chemical, the cumulative weight of the product for each chemical, or quantity of product by Universal Product Code. These examples do not exclude other methods of displaying the quantity sold. Such information may be captured through electronic means, including through electronic data capture through bar code reader or similar technology. Such electronic records must be provided pursuant to paragraph (g) of this section in a human readable form such that the requirements of paragraph (a) of this section are satisfied.

(c) The logbook maintained by the seller must include the prospective purchaser’s name, address, and the date and time of the sale, as follows:

(1) If the purchaser enters the information, the seller must determine that the name entered in the logbook corresponds to the name provided on the identification and that the date and time entered are correct.

(2) If the seller enters the information, the prospective purchaser must verify that the information is correct.

(3) Such information may be captured through electronic means, including through electronic data capture through bar code reader or similar technology.

(d) The regulated seller must include in the written or electronic logbook or display by the logbook, the following notice:

WARNING: Section 1001 of Title 18, United States Code, states that whoever, with respect to the logbook, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or makes any materially false, fictitious, or fraudulent statement or representation, or makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, shall be fined not more than $250,000 if an individual or $500,000 if an organization, imprisoned not more than five years, or both.

(e) The regulated seller must maintain each entry in the written or electronic logbook for not fewer than two years after the date on which the entry is made.

(f) A record under this section must be kept at the regulated seller’s place of business where the transaction occurred, except that records may be kept at a single, central location of the regulated seller if the regulated seller has notified the Administration of the intention to do so. Written notification must be submitted by registered or certified mail, return receipt requested, to the Special Agent in Charge of the DEA Divisional Office for the area in which the records are required to be kept.

(g) The records required to be kept under this section must be readily retrievable and available for inspection and copying by authorized employees of the Administration under the provisions of section 510 of the Act (21 U.S.C. 880).

(h) A record developed and maintained to comply with a State law may be used to meet the requirements of
§ 1314.35 Training of sales personnel.

Each regulated seller must ensure that its sales of a scheduled listed chemical product at retail are made in accordance with the following:

(a) In the case of individuals who are responsible for delivering the products into the custody of purchasers or who deal directly with purchasers by obtaining payments for the products, the regulated seller has submitted to the Administration a self-certification that all such individuals have, in accordance with criteria issued by the Administration, undergone training provided by the regulated seller to ensure that the individuals understand the requirements that apply under this part.

(b) The regulated seller maintains a copy of each self-certification and all records demonstrating that individuals referred to in paragraph (a) of this section have undergone the training.

§ 1314.40 Self-certification.

(a) A regulated seller must submit to the Administration the self-certification referred to in §1314.35(a) in order to sell any scheduled listed chemical product. The certification is not effective for purposes of this section unless, in addition to provisions regarding the training of individuals referred to in §1314.35(a), the certification includes a statement that the regulated seller understands each of the requirements that apply under this part and agrees to comply with the requirements.

(b) When a regulated seller files the initial self-certification, the Administration will assign the regulated seller to one of twelve groups. The expiration date of the self-certification for all regulated sellers in any group will be the last day of the month designated for that group. In assigning a regulated seller to a group, the Administration may select a group with an expiration date that is not less than 12 months or more than 23 months from the date of the self-certification. After the initial certification period, the regulated seller must update the self-certifications annually.

(c) The regulated seller must provide a separate certification for each place of business at which the regulated seller sells scheduled listed chemical products at retail.

§ 1314.42 Self-certification fee; time and method of fee payment.

(a) A regulated seller must pay a fee for each self-certification. For each initial application to self-certify, and for the renewal of each existing self-certification, a regulated seller shall pay a fee of $21.

(b) The fee for self-certification shall be waived for any person holding a current, DEA registration in good standing as a pharmacy to dispense controlled substances.

(c) A regulated seller shall pay the fee at the time of self-certification.

(d) Payment shall be made by credit card.

(e) The self-certification fee is not refundable.

§ 1314.45 Privacy protections.

To protect the privacy of individuals who purchase scheduled listed chemical products, the disclosure of information in logbooks under §1314.30 is restricted as follows:

(a) The information shall be disclosed as appropriate to the Administration and to State and local law enforcement agencies.

(b) The information in the logbooks shall not be accessed, used, or shared for any purpose other than to ensure compliance with this title or to facilitate a product recall to protect public health and safety.

(c) A regulated seller who in good faith releases information in a logbook to Federal, State, or local law enforcement authorities is immune from civil liability for the release unless the release constitutes gross negligence or intentional, wanton, or willful misconduct.

§ 1314.50 Employment measures.

A regulated seller may take reasonable measures to guard against employing individuals who may present a