

Monitoring the Sale of Products Containing Ephedrine, Pseudoephedrine, or Phenylpropanolamine

This Act establishes criteria to monitor buying and selling products that contain Ephedrine, Pseudoephedrine, or Phenylpropanolamine. The law makes it illegal to purchase certain amounts of these products during certain times.

The bill requires information about such purchases that is gathered from purchasers at the time of sale be entered into an electronic log instead of a written log. Such information must be transmitted to a data collection system in real time and generate a stop sale alert if the sale of Ephedrine, Pseudoephedrine, or Phenylpropanolamine would result in a violation of law. The Act provides that a retailer who receives a stop sale alert must not complete the sale unless they fear they will be harmed by the purchaser. It directs the state law enforcement division to set up an electronic monitoring system to serve as the repository for the information collected under the Act.

This draft legislation differs in several ways from the SSL draft “[Real Time Electronic Logbook for a Pharmacy to Record Purchases of Psuedoephedrine and Other Similar Substances](#)” in the 2009 *Suggested State Legislation* volume.

First, this legislation integrates all state precursor sales data into a National Precursor Log Exchange. That exchange currently operates in more than 25,000 retailers nationwide, including mandatorily in ten states. This is accomplished through the MOU specified by the bill to be executed by the National Drug Diversion Investigators Association. In practice, this results in sales being blocked and tracked regardless of state lines, and made immediately available to some 5000 law enforcement officers via a secure web-site.

Second, this law requires provision of the transactional data to a state law enforcement agency. This allows that division to feed their criminal intelligence data base, resulting in much more effective intelligence for investigators, all within the parameters of state and federal law.

Finally, this bill requires that there be no cost to any state government agency, retailer, or pharmacy for any of these services. In fact, all support, training, implementation, and administration to the extent requested are performed at no cost to said entities. This is accomplished by the required sponsorship of the manufacturers of these over-the-counter medicines, in order that these products can continue to be sold in the state.

Submitted as:

South Carolina

[Act 242 of 2010](#)

Status: Enacted into law in 2010.

Suggested State Legislation

(Title, enacting clause, etc.)

1 Section 1. [*Short Title.*] This Act shall be cited as “An Act to Establish Criteria to
2 Monitor Buying and Selling Products Containing Ephedrine, Pseudoephedrine, or
3 Phenylpropanolamine.”
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5 Section 2. [*Procedures for Selling, Reporting, and Restricting Certain Products*
6 *Containing Ephedrine, Pseudoephedrine, or Phenylpropanolamine.*]

7 (A) Nonprescription products whose sole active ingredient is Ephedrine,
8 Pseudoephedrine, or Phenylpropanolamine can be offered for retail sale only if sold in blister
9 packaging. The retailer shall ensure that such products are not offered for retail sale by self-
10 service but only from behind a counter or other barrier so that such products are not directly
11 accessible by the public but only by an employee or agent of the retailer.

12 (B) (1) A retailer may not sell to an individual in any single day a nonprescription
13 product or a combination of nonprescription products containing more than [3.6] grams of
14 Ephedrine, Pseudoephedrine, or Phenylpropanolamine; and a retailer may not sell to an
15 individual in a [thirty-day] period a nonprescription product or a combination of nonprescription
16 products containing more than [nine] grams of Ephedrine, Pseudoephedrine, or
17 Phenylpropanolamine.

18 (2) An individual may not purchase in any single day a nonprescription product or
19 a combination of nonprescription products containing more than [3.6] grams of Ephedrine,
20 Pseudoephedrine, or Phenylpropanolamine; and an individual may not purchase in a [thirty-day]
21 period a nonprescription product or a combination of nonprescription products containing more
22 than [nine] grams of Ephedrine, Pseudoephedrine, or Phenylpropanolamine.

23 (C) It is unlawful for a retailer to purchase any product containing Ephedrine,
24 Pseudoephedrine, or Phenylpropanolamine from any person or entity other than a manufacturer
25 or a wholesale distributor registered by the United States Drug Enforcement Administration.

26 (D) (1) A retailer selling nonprescription products containing Ephedrine,
27 Pseudoephedrine, or Phenylpropanolamine shall require the purchaser to produce a government
28 issued photo identification showing the date of birth of the person and require the purchaser to
29 sign an electronic log showing the date and time of the transaction, the person's name and
30 address, the type, issuing governmental entity, identification number, and the amount of the
31 compound, mixture, or preparation. The retailer shall determine that the name entered in the log
32 corresponds to the name on the identification and that the date and time entered are correct and
33 shall enter in the log the name of the product and the quantity sold. The retailer shall ensure that
34 the product is delivered directly into the custody of that purchaser. The log must include a notice
35 to purchasers that entering false statements or misrepresentations in the log may subject the
36 purchaser to criminal penalties.

37 (2) Before completing a sale of a product regulated by this section, the retailer
38 electronically shall transmit the information entered in the log to a data collection system
39 provided by the National Association of Drug Diversion Investigators, or a successor or similar
40 entity. The system must collect this data in real time and generate a Stop Sale Alert if the sale
41 would result in a violation of subsection (B) or a federal quantity restriction, which must be
42 assessed on the basis of sales or purchases made in any state to the extent that information is
43 available in the data collection system. If the retailer receives a Stop Sale Alert, the retailer must
44 not complete the sale unless the retailer, upon notifying the purchaser the sale cannot be
45 completed, reasonably fears bodily harm if they deny the sale due to the Stop Sale Alert. A
46 product regulated by this section may not be sold without being reported to the data collection
47 system unless the system is experiencing temporary technical difficulties that prevent a retailer
48 from reporting the information to the system, and in that case, the retailer shall enter the
49 necessary information in a written log, which must subsequently be entered into the electronic
50 log within [three business days] of each business day that the electronic log was not operational.
51 A retailer using a written log under these circumstances is immune from liability during the time
52 the system is temporarily disabled.

53 (3) Any information entered in the electronic log that is retained by a retailer, or
54 information maintained by a retailer pursuant to subsection (J)(2), is confidential and not a public
55 record as defined in Section 30-4-20(c) of the Freedom of Information Act. A retailer or an
56 employee or agent of a retailer who in good faith releases information in a log to federal, state, or
57 local law enforcement authorities is immune from civil liability for the release unless the release
58 constitutes gross negligence or intentional, wanton, or willful misrepresentation.

59 (E) Except as authorized by this section, it is unlawful for any person to possess, have
60 under their control, manufacture, deliver, distribute, dispense, administer, purchase, sell, or
61 possess with intent to distribute, any substance containing any amount of Ephedrine,
62 Pseudoephedrine, or Phenylpropanolamine or any of their salts, optical isomers, or salts of
63 optical isomers which have been altered from an original condition so as to be powdered,
64 liquefied, dissolved, solvated, or crushed. This subsection does not apply to any of the substances
65 identified within this subsection which are possessed or altered for a legitimate medical purpose
66 as directed by a person licensed under [insert citation] and authorized to prescribe legend drugs.

67 (F) It is unlawful for a person to enter false statements or misrepresentations on the log
68 required pursuant to subsection (D)(1).

69 (G) This section preempts all local ordinances or regulations governing the retail sale or
70 purchase of nonprescription products containing Ephedrine, Pseudoephedrine, or
71 Phenylpropanolamine except such local ordinances or regulations that existed on or before
72 [insert date.]

73 (H) (1) Except as otherwise provided in this section, it is unlawful for a retailer
74 knowingly to violate subsection (A), (B)(1), (C), (D)(1), or (D)(2), and it is unlawful for a person
75 knowingly to violate subsection (B)(2), (E), or (F).

76 (2) A retailer convicted of a violation of subsection (A) or (B)(1) is guilty of a
77 misdemeanor and, upon conviction for a [first] offense, must be fined not more than [five
78 thousand] dollars and, upon conviction for a [second] or subsequent offense, must be fined not
79 more than [ten thousand] dollars.

80 (3) A retailer convicted of a violation of subsection (C) is guilty of a misdemeanor
81 and, upon conviction for a [first] offense, must be imprisoned not more than [one year] or fined
82 not more than [one thousand] dollars, or both and, upon conviction for a [second] or subsequent
83 offense, must be imprisoned not more than [three years] or fined not more than [five thousand]
84 dollars, or both.

85 (4) A retailer convicted of a violation of subsection (D)(1), (D)(2), or (J)(2) is
86 guilty of a misdemeanor and, upon conviction for a [first] offense, must be fined not more than
87 [one thousand] dollars and not less than [five hundred] dollars. Upon conviction for a [second]
88 offense, a retailer must be fined not more than [five thousand] dollars and not less than [one
89 thousand] dollars. Upon conviction for a [third] or subsequent offense, a person must be fined
90 not more than [ten thousand] dollars and not less than [five thousand] dollars.

91 (5) A person convicted of a violation of subsection (B)(2) or (E) is guilty of a
92 felony and, upon conviction for a [first] offense, must be imprisoned not more than [five] years
93 and fined not more than [five thousand] dollars. The court, upon approval from the solicitor, may
94 request as part of the sentence, that the offender enter and successfully complete a drug treatment
95 program. For a [second] or subsequent offense, the offender is guilty of a [felony] and, upon
96 conviction, must be imprisoned not more than [ten] years or fined not less than [ten thousand]
97 dollars.

98 (6) A person convicted of a violation of subsection (F), upon conviction for a
99 [first] offense, is guilty of a misdemeanor and must be fined not more than [one thousand]
100 dollars and, upon conviction for a [second] or subsequent offense, is guilty of a felony and must
101 be fined not more than [five thousand] dollars.

102 (7) It is an affirmative defense to a violation of subsection (A), (C), or (D)(1) if a
103 retailer provided the training, maintained records, and obtained employee and agent statements
104 of agreement required by Subsection (I) for all employees and agents at the retail location where
105 the violation occurred and at the time the violation occurred.

106 (8) It is an affirmative defense to completing a sale following receipt of a Stop
107 Sale Alert received pursuant to subsection (D)(2) if the retailer, upon notifying the purchaser the
108 sale cannot be completed, reasonably fears bodily harm if they deny the sale due to the Stop Sale
109 Alert.

110 (I) A retailer shall provide training on the requirements of this section to all agents and
111 employees who are responsible for delivering the products regulated by this section into the
112 custody of purchasers or who deal directly with purchasers by obtaining payments for the
113 products. A retailer shall obtain a signed, written agreement from each employee or agent that
114 the employee or agent agrees to comply with the requirements of this section. The retailer shall
115 maintain records demonstrating that these employees and agents have been provided this training
116 and the documents executed by the retailer's employees and agents agreeing to comply with this
117 section.

118 (J) (1) The following are exempt from the electronic log requirements of this section
119 but shall maintain a written log containing the information required to be entered in the
120 electronic log, as provided for in subsection (D)(1):

121 (a) a retailer that only sells single dose packages of nonprescription
122 Ephedrine, Pseudoephedrine, or Phenylpropanolamine;

123 (b) A pharmacy that does not have a compatible point of sale system.

124 (2) A retailer who maintains a written log pursuant to this subsection shall retain
125 the written log for [two] years after which the log may be destroyed. The log must be made
126 available for inspection within [twenty-four] hours of a request made by a local, state, or federal
127 law enforcement officer.

128 (3) A retailer who violates the requirements of maintaining a written log as
129 provided for in subsection (J)(2) is subject to the penalties provided for in subsection (H)(4).

130 (K) The sheriff or chief of police shall monitor and determine if retailers, other than
131 licensed pharmacies, are in compliance with the provisions of this section by ensuring that a
132 retailer:

133 (1) Is entering all sales of a product regulated by this section in an electronic log
134 as required by this section;

135 (2) If not maintaining an electronic log, is exempt as provided for in subsection
136 (J)(1), and is continuing to maintain the written log as provided for in subsection (J);

137 (3) Is not selling products regulated by this section.

138 (L) This section does not apply to:

139 (1) Pediatric products labeled pursuant to federal regulation as primarily intended
140 for administration to children under [twelve] years of age according to label instructions;

141 (2) Products that the [board of pharmacy], upon application of a manufacturer,
142 exempts because the product is formulated in such a way as to effectively prevent the conversion
143 of the active ingredient into Methamphetamine or its salts or precursors; and

144 (3) A purchase of a single sales package containing not more than [sixty]
145 milligrams of Pseudoephedrine.

146 (M) For purposes of this section "retailer" means a retail distributor, including a
147 pharmacy, where Ephedrine, Pseudoephedrine, or Phenylpropanolamine products are available
148 for sale and does not include an employee or agent of a retailer.

149
150 Section 3. *[Electronic Monitoring System.]*

151 (A) The [state law enforcement division (SLED)] shall serve as the statewide, central
152 repository for log information submitted electronically in real time to the data collection system
153 pursuant to section (D)(2) of this Act and transferred to [SLED] in order to monitor the sales and
154 purchases of nonprescription products containing Ephedrine, Pseudoephedrine, or
155 Phenylpropanolamine. [SLED] shall maintain the information received from the data collection
156 system in [SLED's Electronic Monitoring System] and must not be charged any vendor or other
157 fees associated with the requirements of this Act.

158 (B) The data collection system upon which [SLED's Electronic Monitoring System] is
159 based must have the capability to:

160 (1) Calculate state and federal sales and purchase limitations for Ephedrine,
161 Pseudoephedrine, and Phenylpropanolamine;

162 (2) Match similar purchaser identification information;

163 (3) Alert retailers of potential illegal sales and purchases;

164 (4) Allow a retailer to override an alert of a potential illegal sale or purchase;

165 (5) Receive Ephedrine, Pseudoephedrine, and Phenylpropanolamine sales data
166 from retailers in the format in which the data was submitted so that retailers are not required to
167 use any one particular vendor's product to comply with the requirements of this section and
168 section (D)(2); and

169 (6) Interface with existing and future operational systems used by pharmacies at
170 no cost to these pharmacies.

171 (C) The data transmitted to the data collection system must be recorded in real time and
172 the storage of this data must be housed by an information technology company operating under
173 strict security standards that only may be accessed by local, state, or federal law enforcement
174 authorized by [SLED].

175 (D) (1) No fee may be charged to retailers for access to the data collection system to
176 which information is required to be transmitted pursuant to section (D)(2) of this Act, and no
177 other fee or assessment can be imposed on retailers to fund program operations.

178 (2) No fee may be charged to local, state, or federal law enforcement officers or
179 entities for access to or retention, analysis, or use of information in the system concerning sales
180 and purchases of nonprescription Ephedrine, Pseudoephedrine, and Phenylpropanolamine that
181 violate or potentially violate subsection (B)(1) or (2).

182 (E) The information in [SLED's Electronic Monitoring System] is confidential and not a
183 public record as defined in [insert citation]. [SLED] only shall provide access to information
184 maintained in the monitoring system to:

185 (1) a local, state, or federal law enforcement official, a state attorney, or a United
186 States Attorney;

187 (2) a local, state, or federal official who requests access to the monitoring system
188 for the purpose of facilitating a product recall necessary to protect public health and safety; and

189 (3) the [board of pharmacy] for the purpose of investigating misconduct or a
190 suspicious transaction committed by a retailer, a pharmacist, or an employee or agent of a
191 pharmacy.

192 (F) for purposes of this section "retailer" means a retail distributor, including a pharmacy,
193 where Ephedrine, Pseudoephedrine, or Phenylpropanolamine products are available for sale and
194 does not include an employee or agent of a retailer.

195 (G) The [division] shall promulgate regulations necessary to carry out its responsibilities
196 under this section.

197 (H) Nothing in this Act prohibits [SLED] or any retailer from participating in other data
198 submission, collection, or monitoring systems that monitor the sales and purchases of
199 nonprescription products containing Ephedrine, Pseudoephedrine, or Phenylpropanolamine.

200

201 Section 4. [*Memorandum of Agreement.*] Before [insert date], the [State Law
202 Enforcement Division (SLED)] shall enter into a Memorandum of Agreement with the National
203 Association of Drug Diversion Investigators (NADDI), or a successor or other entity, to identify
204 the roles and responsibilities of [SLED] and NADDI, or a successor or other entity, in carrying
205 out the collection of sales and purchase data of Ephedrine, Pseudoephedrine, or
206 Phenylpropanolamine products and the transference of this information to the [state law
207 enforcement division] as provided for in this Act. The Memorandum must provide that the data
208 and information in [SLED's Electronic Monitoring System] is property of the state and that
209 NADDI will provide [SLED] with that data and information at least [four] times a year in a
210 format agreed to by [SLED] and NADDI and that is consistent with the most recent standards
211 adopted by the American Society for Automation in Pharmacy (ASAP), as well as the most
212 recent standards adopted by the National Information Exchange Model (NIEM).

213

214 Section 5. [*Implementation Date.*] The electronic logbook, central data collection system,
215 and the [state law enforcement division electronic monitoring system] required pursuant to
216 section 3 of this Act must be implemented by [insert date].

217

218 Section 6. [*Severability.*] [Insert severability clause.]

219

220 Section 7. [*Repealer.*] [Insert repealer clause.]

221

222 Section 8. [*Effective Date.*] [Insert effective date.]