

SOUTH CAROLINA**PRODUCTS:**

- Single entity and combination pseudoephedrine (PSE) and ephedrine (EPH)

PRODUCT EXEMPTIONS:

- Pediatric products labeled pursuant to federal regulation as primarily intended for administration to children under 12 years according to label instructions are exempt from all requirements; (SC ST § 44–53–398)
- Products exempted by the Board of Pharmacy (upon application of a manufacturer) because the product is formulated to effectively prevent conversion of the active ingredient into methamphetamine are exempt from all requirements; (SC ST § 44–53–398)
- Purchase of a single sales package containing not more than 60 mg of PSE exempt from all sales limits, restrictions, recordkeeping, and placement requirements are exempt from all requirements; (SC ST § 44–53–398) and
- Combination PSE and EPH products need not be sold in blister packaging and such products are also exempt from placement, ID and log requirements. (SC ST § 44–53–398)

SALES LIMITS:

- Retailer may not sell to an individual in any single day more than 3.6g of PSE/EPH/PPA. (SC ST § 23–3–1200)
- Retailer may not sell to an individual more than 9g of EPH/PSE/PPA within a 30-day period. (SC ST § 23–3–1200)

PURCHASE LIMITS:

- Individual may not purchase any single day more than 3.6g of EPH/PSE/PPA. (SC ST § 44–53–398)
- Individual may not purchase more than 9g of EPH/PSE/PPA within a 30-day period. (SC ST § 44–53–398)

SALES RESTRICTIONS:

- Single entity PSE and EPH may only be offered for retail sale in blister packaging. (SC ST § 44–53–398)
- Retailer must ensure that any PSE or EPH product is delivered directly into the custody of the purchaser. (SC ST § 44–53–398)

ID REQUIREMENTS:

- For single entity PSE and EPH products, the retailer must require purchasers to produce a government issued photo ID showing the date of birth. (SC ST § 44–53–398)

RECORDKEEPING REQUIREMENTS:

- For single entity PSE and EPH products, the retailer require purchasers to sign a electronic log showing the date and time of the transaction, the purchaser's name and address, the type, the issuing governmental entity , identification number , and the amount of the compound, mixture, or preparation. It is the responsibility of the retailer to determine that the name entered in the log corresponds to the name on the ID and that the date and time entered are correct. The retailer must enter in the log the name of the product and the quantity sold; (SC ST § 23-3-1200)
- The log must include a notice to purchasers that entering false statements or misrepresentations in the logbook may subject the purchaser to criminal penalties; (SC ST § 23-3-1200)
- Retailers must retain the log for 2 years after which the log may be destroyed;
- The log must be made available for inspection within 24 hours of a request made by a local, state, or federal law enforcement officer; (SC ST § 23-3-1200) and
- A log retained by a retailer is confidential and not a public record available via the Freedom of Information Act. (SC ST § 23-3-1200)

PRODUCT PLACEMENT:

- Single entity PSE and EPH products may only be sold from behind a counter or other barrier so that products are not directly accessible by the public without the assistance of an employee or agent of the retailer. Such products may not be offered for retail sale by self-service. (SC ST § 44-53-398)

THE STATE LAW ENFORCEMENT ELECTRONIC DIVISION (SLED):

- The State Law Enforcement Division (SLED) which will be implement January 1, 2011 shall serve as the statewide, central repository for log information submitted electronically in real time to the data collection system. SLED will monitor the sales and purchases of nonprescription products containing EPH, PSE, and PPA. (SC ST § 23-3-1200)
- SLED shall maintain the information received from the data collection system in SLED's electronic monitoring system and must not be charged any vendor or other fees associated with the requirements of this chapter. (SC ST § 23-3-1200)
- Data collection system upon which SLED's electronic monitoring system is based must have the capability to: calculate state and federal sales and purchase limitations for EPH, PSE, and PPA; match similar purchaser identification information; alert retailers of potential illegal sales and purchases; allow a retailer to override an alert of a potential illegal sale or purchase; receive EPH, PSE, and PPA sales data from retailers in the format in which the data was submitted so that retailers are not required to use any one particular vendor's product to comply with the requirements of this section and Section 44-53-398(D)(2); and

interface with existing and future operational systems used by pharmacies at no cost to these pharmacies. (SC ST § 23–3–1200)

- Data transmitted to the data collection system must be recorded in real time and the storage of this data must be housed by an information technology company operating under strict security standards that only may be accessed by local, state, or federal law enforcement authorized by SLED. (SC ST § 23–3–1200)
- No fee may be charged to retailers for access to the data collection system to which information is required to be transmitted, and no other fee or assessment may be imposed on retailers to fund program operations. (SC ST § 44–53–398)
- No fee may be charged to local, state, or federal law enforcement officers or entities for access to or retention, analysis, or use of information in the system concerning sales and purchases of nonprescription ephedrine, pseudoephedrine, and phenylpropanolamine that violate or potentially violate subsection 44–53–398(B)(1) or (2). SC ST § 23–3–1200
- The information in SLED's electronic monitoring system is confidential and not a public record as defined in the Freedom of Information Act. (SC ST § 44–53–398)
- SLED only shall provide access to information maintained in the monitoring system to: a local, state, or federal law enforcement official, a state attorney, or a United States attorney; a local, state, or federal official who requests access to the monitoring system for the purpose of facilitating a product recall necessary for the protection of the public health and safety; and the Board of Pharmacy for the purpose of investigating misconduct or a suspicious transaction committed by a retailer, a pharmacist, or an employee or agent of a pharmacy. (SC ST § 44–53–398)
- “Retailer” means a retail distributor, including a pharmacy, where ephedrine, pseudoephedrine, or phenylpropanolamine products are available for sale and does not include an employee or agent of a retailer. (SC ST § 44–53–398)
- Memorandum of agreement:
 - Before January 1, 2011, the State Law Enforcement Division (SLED) shall enter into a memorandum of agreement with the National Association of Drug Diversion Investigators (NADDI), or a successor or other entity, to identify the roles and responsibilities of SLED and NADDI, or a successor or other entity, in carrying out the collection of sales and purchase data of ephedrine, pseudoephedrine, or phenylpropanolamine products and the transference of this information to the State Law Enforcement Division as provided for in this act. The memorandum must provide that the data and information in SLED's electronic monitoring system is property of the State and that NADDI will provide SLED with that data and information at least four times a year in a format agreed to by SLED and NADDI and that is consistent with the most recent standards adopted by the American Society for Automation in Pharmacy (ASAP), as well as the

most recent standards adopted by the National Information Exchange Model (NIEM). (SC ST § 44-53-398)

SELLER RESPONSIBILITIES: STOP SALES; REPORTING

- Before completing a sale of a product, the retailer electronically shall transmit the information entered in the log to a data collection system provided by the National Association of Drug Diversion Investigators, or a successor or similar entity. (SC ST § 44-53-398)
- The system must collect this data in real time and generate a stop sale alert if the sale would result in a violation or a federal quantity restriction, which must be assessed on the basis of sales or purchases made in any state to the extent that information is available in the data collection system. (SC ST § 44-53-398)
- If the retailer receives a stop sale alert, the retailer must not complete the sale unless the retailer, upon notifying the purchaser the sale cannot be completed, reasonably fears bodily harm if he denies the sale due to the stop sale alert. (SC ST § 44-53-398)
- A product regulated by this section may not be sold without being reported to the data collection system unless the system is experiencing temporary technical difficulties that prevent a retailer from reporting the information to the system, and in that case, the retailer shall enter the necessary information in a written log, which must subsequently be entered into the electronic log within three business days of each business day that the electronic log was not operational. (SC ST § 44-53-398)
- A retailer using a written log under these circumstances is immune from liability during the time the system is temporarily disabled. (SC ST § 44-53-398)

EMPLOYEE TRAINING:

- Retailers must provide training on the requirements of law restricting the sales of and access to PSE and EPH products for all agents and employees who are responsible for delivering such products into the custody of purchasers or who deal directly with purchasers by obtaining payments for the products; (SC ST § 44-53-398) and
- Retailers must obtain a signed, written agreement from each employee or agent that the employee or agent agrees to comply with the requirements of the law and maintain these in their records. (SC ST § 44-53-398)

PENALTIES:

- Violations of sales limits, blister pack sales restrictions and placement requirements are misdemeanors that on first offense, are subject to a \$5000 maximum fine and \$10,000 maximum fine for second and subsequent offenses; (SC ST § 44-53-398)

- False log entries are a misdemeanor offense and subject to a \$1000 maximum fine for the first offense. Second and subsequent offenses are a felony and subject to a \$5000 maximum fine; (SC ST § 44-53-398)
- Retailers who purchase PSE and EPH products from anyone other than a manufacturer or wholesale distributor registered by DEA are guilty of a misdemeanor and subject to up to one year imprisonment, a \$1000 maximum fine, or both, for the first offense. Second and subsequent offenses are a misdemeanor and subject to up to 3 years imprisonment, a fine of up to a \$5000 maximum fine, or both; (SC ST § 44-53-398) and
- Retailers who violate ID and log requirements are guilty of a misdemeanor and are subject to a minimum \$500 / maximum \$1000 fine for the first offense, \$1000 minimum / \$5000 maximum for second offense, and \$5000 minimum / \$10,000 maximum for third and subsequent offenses. (SC ST § 44-53-398)

AFFIRMATIVE DEFENSE:

- It is an affirmative defense to a violation relating to blister pack sales restrictions, placement requirements, false log entries, ID and log requirements if a retailer provided training, maintained records, and obtained employee and agent “statements of agreement” for all employees and agents at the retail location where the violation occurred and at the time the violation occurred. A “statement of agreement” is a signed, written agreement from each employee or agent of the retailer that the employee or agent agrees to comply with the requirements of the law with respect to sales limits and restrictions of PSE and EPH products. (SC ST § 44-53-398)

RETAILER LIABILITY EXEMPTION:

- A retailer or an employee or agent of a retailer who in good faith releases information in a log 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 misrepresentation. (SC ST § 44-53-398)
- The following are exempt from the electronic log requirements but shall maintain a written log containing the information required to be entered in the electronic log: a retailer that only sells single dose packages of nonprescription ephedrine, pseudoephedrine, or phenylpropanolamine; pharmacy that does not have a compatible point of sale system. (SC ST § 44-53-398)

WHOLESALE DISTRIBUTION REQUIREMENTS:

- It is unlawful for a retailer to purchase any PSE or EPH product from any person or entity other than a manufacturer or a wholesale distributor registered by DEA. (SC ST § 44-53-398)

PREEMPTION:

- All local ordinances or regulations, except for those that existed on or before December 31, 2004, are preempted. (SC ST § 44-53-398)