Pseudoephedrine Protocol

A. SCOPE:
A pharmacy’s distribution or sale of any Schedule V PSE (Pseudoephedrine) product currently available without a prescription from a licensed practitioner.

B. PURPOSE:
The purpose of this protocol is to assist pharmacists in providing safe and effective cough and cold therapy related to the sale, distribution and use of PSE and PSE containing products in New Mexico. In addition, this protocol is being used to decrease the diversion of these products via the requirement that a valid pharmacy-patient relationship be established before the sale or distribution of any PSE or PSE combination product commence.

C. GUIDELINES:
Distribution of PSE shall be limited to patients with an established relationship with the pharmacy in which the medication is being distributed. Distribution of PSE containing products shall be in accordance with individual product labeling and packaging for dosage information, age limits, precautions and contraindications to use. If a patient requires a PSE containing medication for an off label use or in a dose inconsistent with manufacturer recommendations of respective product, a prescription from a licensed practitioner is required. A pharmacist or pharmacist intern may refuse to distribute pseudoephedrine to any individual based on their professional judgment. A pharmacy technician may distribute or sell PSE to a patient pursuant to requirements set forth in the board approved pseudoephedrine protocol.

D. INDICATIONS:
PSE is an oral decongestant indicated for the short term relief of cough and cold symptoms. Indications for each product may differ depending on other active ingredients in the product; specific information may be located on product packaging.

E. QUANTITY LIMITS:
The sale of PSE by a registered pharmacist or intern shall be subject to distribution limits of no more than 3.6 grams per day or more than a total of 9 grams of a product, mixture or preparation containing pseudoephedrine within a thirty-day period.

F. CONTRAINDICATIONS:
The pharmacist should consult individual product packaging, manufacturer recommendations or other professional references in regards to contraindications, precautions, drug-drug and drug-disease state interactions pertaining to PSE and PSE containing products. General precautions to PSE include but are not limited to: diabetes, glaucoma, heart problems (such as myocardial infarction, chest pain/angina, and congestive heart failure), fast/irregular heartbeat, high blood pressure, kidney disease, hyperthyroidism, and difficulty urinating etc. This is not an all-inclusive list and pharmacists and interns should use professional judgment based on individual characteristics of each patient. A pharmacist or intern may refuse to distribute PSE based on their professional judgment.

G. HEALTH SCREENING:
A general patient interview shall be performed by a pharmacist or intern to ensure that the patient does not have any contraindications or precautions to the use of PSE according to the manufacturer’s labeling. This interview will also be used to determine if the need for PSE by the requesting patient meets the manufacturer’s guidelines for product use. This interview should address concurrent disease states, medication history, indication for use of PSE, and drug allergies. A patient profile, consistent with the requirements set forth in NMAC 16.19.4.16.C, shall be created and maintained by a pharmacist or pharmacist intern in order to establish and maintain a pharmacy-patient relationship. Upon establishing a valid pharmacy-patient relationship, a pharmacist, pharmacist intern or pharmacy technician may sell or distribute PSE or PSE containing products.
H. PATIENT EDUCATION:
The product packaging or individualized medication hand out should be used to help the patient understand the proper use of PSE containing products. A pharmacist or pharmacist intern shall personally offer to counsel on matters which will enhance or optimize drug therapy with each patient or the patient's agent.

I. RECORDS:
   a. The pharmacist or intern shall create and maintain a patient data base consistent with 16.19.4.16.C in order to establish a pharmacy-patient relationship for the distribution of PSE. The pharmacist is responsible for fulfilling the duties of a pharmacist as set forth in 16.19.4.16 A through G. A reasonable effort must be made to obtain, record and maintain at least the following information in the patient profile:
      i. name, address, telephone number, date of birth or age and gender of patient;
      ii. individual medical history, if significant, including disease state or states, known allergies and drug reactions and a comprehensive list of medications and relevant devices;
      iii. relevant pharmacist comments; and
   b. the person purchasing, receiving or otherwise acquiring the compound, mixture or preparation shall produce a valid driver’s license or other government-issued photo identification showing the date of birth; and
   c. records of the sale shall be logged according to 16.19.20.53