

6800.8001 POLICY AND PROCEDURES MANUAL.

To obtain a pharmacy license as a parenteral-enteral home health care pharmacy, a policy and procedures manual shall be available for inspection at the pharmacy. The manual shall be reviewed and revised on an annual basis. The manual shall include the policy and procedures for:

- A. compliance with the official compendium United States Pharmacopeia, chapter 797;
- B. clinical services;
- C. cytotoxics handling, storage, and disposal;
- D. disposal of unused supplies and medications;
- E. drug destruction and returns;
- F. drug dispensing;
- G. drug labeling and relabeling;
- H. drug storage;
- I. duties and qualifications for professional and nonprofessional staff;
- J. equipment;
- K. handling of infectious waste, pharmaceutical waste, and hazardous waste;
- L. infusion devices and drug delivery systems;
- M. investigational drugs;
- N. obtaining a protocol on investigational drugs from the principal investigator;
- O. public safety;
- P. quality assurance procedures, including:
 - (1) recall procedures;
 - (2) storage and dating;
 - (3) educational procedures for professional staff, nonprofessional staff, and patients;
 - (4) sterile procedures including a log of the temperature of the refrigerator, routine maintenance, and report of hood certification; and
 - (5) sterility testing of the product;
- Q. record keeping;
- R. reference materials;

- S. sanitation;
- T. security;
- U. sterile product preparation procedures; and
- V. transportation.

Statutory Authority: *MS s 151.06; 152.02*

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