## PROFESSIONAL SERVICES

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## CHAPTER 75 PHARMACY

## 3-7.8B continued

- · Blue Book or Red Book
- Federal and State laws and regulations pertaining to drugs, narcotics, hypnotics, alcohol and spirituous liquors and State and local pharmacy laws and regulations. 1/
- Current Therapy, Conn or Drugs of Choice, Model1 1/
- · Drug and Cosmetic Review Magazine
- · Journal of the American Pharmaceutical Association
- · Journal of Pharmaceutical Sciences
- · American Journal of Hospital Pharmacy
- · American Professional Pharmacist
- C. The pharmacy shall also maintain files containing literature on the newer therapeutic agents, and the house organs, catalogs and price list of pharmaceutical manufacturers.

## 3-7.9 <u>INVESTIGATIONAL DRUGS</u>

Investigational drugs, and drugs not available in interstate commerce, must have the approval of the Chief, Division of Indian Health, for authority to procure and use.

- A. Prior to requesting approval for the clinical trial of any drug, the proposed study will be cleared by the Area Pharmacy and Therapeutics Committee, which is prescribed in Section 3-7.5 of this Chapter, and the Area Research Committee, which is prescribed in Part I Chapter 7 of this manual. It is recommended that the Committees consider such proposals in the light of current knowledge of the drug and other drugs in the same therapeutics class, and that a scientific clinical research protocol be formulated to evaluate the particular agent.
- B. Research protocol should set forth the laboratory and the clinical aspects of the study, make provisions for control, assure the availability of adequate laboratory and other diagnostic and testing resources for the particular study or follow-up, and indicate the basis upon which it is planned to make comparisons with accepted pharmacological agents.
- C: The principal investigator must be considered an expert qualified by scientific training and experienced to investigate the safety of drugs.

<sup>1/</sup> These books and publications shall be available at stations without pharmacies with a full-time Medical Officer.