PHARMACISTS

Effective September 1, 2015

<u>Initial training:</u> All pharmacists who compound sterile preparations for administration to patients or supervise pharmacy technicians and pharmacy technician trainees compounding sterile preparations shall:

- (1) complete through a single course, a minimum of 20 hours of instruction and experience in the areas listed below. The training shall be obtained through completion of a recognized course in an accredited college of pharmacy or a course sponsored by an ACPE accredited provider;
- (2) complete a structured on-the-job didactic and experiential training program at this pharmacy which provides sufficient hours of instruction and experience in the facility's sterile compounding processes and procedures. The training may not be transferred to another pharmacy unless the pharmacies are under common ownership and control and use a common training program; and
- (3) possess knowledge about aseptic processing; quality control and quality assurance as related to environmental, component, and finished preparation release checks and tests; chemical, pharmaceutical, and clinical properties of drugs; container, equipment, and closure system selection; and sterilization techniques.

Renewal: In order to renew a license to practice pharmacy, during the previous licensure period, a pharmacist engaged in sterile compounding shall complete a minimum of:

- (1) two hours of ACPE-accredited continuing education relating to one or more of the areas listed below if the pharmacist is engaged in compounding low and medium risk sterile preparations; or
- (2) four hours of ACPE-accredited continuing education relating to one or more of the areas listed below if the pharmacist is engaged in compounding high risk sterile preparations.

The didactic and experiential training shall include instruction, experience, and demonstrated proficiency in the following areas:

- aseptic technique;
- critical area contamination factors:
- environmental monitoring;
- structure and engineering controls related to facilities;
- equipment and supplies;
- sterile preparation calculations and terminology;
- sterile preparation compounding documentation;
- quality assurance procedures;
- aseptic preparation procedures including proper gowning and gloving technique;
- handling of hazardous drugs, if applicable;
- cleaning procedures; and
- general conduct in the clean room.