Sterile Compounding Initial Certification Requirements For Pharmacy Technicians

Initial Sterile Compounding Certification – 219.133(c)(3)(B)(ii)

- (ii) All pharmacy technicians and pharmacy technician trainees who compound sterile preparations for administration to patients shall:
 - (I) have initial training obtained either through completion of:
 - (-a-) a single course, a minimum of 40 hours of instruction and experience in the areas listed in paragraph (4)(D) of this subsection. Such training shall be obtained through completion of a course sponsored by an ACPE accredited provider which provides 40 hours of instruction and experience; or
 - (-b-) a training program which is accredited by the American Society of Health-System Pharmacists.

(II) and

- (-a-) 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. Such training may not be transferred to another pharmacy unless the pharmacies are under common ownership and control and use a common training program; and (-b-) possess knowledge about:
 - (-1-) aseptic processing;
 - (-2-) quality control and quality assurance as related to environmental, component, and finished preparation release checks and tests;
 - (-3-) chemical, pharmaceutical, and clinical properties of drugs;
 - (-4-) container, equipment, and closure system selection; and
 - (-5-) sterilization techniques.

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Sterile Compounding CE Requirements for Maintaining Certification For Pharmacy Technicians

Renewing a Sterile Compounding Certification – 219.133(c)(3)(B)(v)

- (v) In order to renew a registration as a pharmacy technician, during the previous registration period, a pharmacy technician engaged in sterile compounding shall complete a minimum of:
 - (I) two hours of ACPE accredited continuing education relating to one or more of the areas listed in paragraph (4)(D) of this subsection if the pharmacy technician is engaged in compounding low and medium risk sterile preparations; or
 - (II) four hours of ACPE accredited continuing education relating to one or more of the areas listed in paragraph (4)(D) of this subsection if the pharmacy technician is engaged in compounding high risk sterile preparations.

Paragraph (4)(D) as referenced above is as follows:

- (D) The didactic and experiential training shall include instruction, experience, and demonstrated proficiency in the following areas:
 - (i) aseptic technique;
 - (ii) critical area contamination factors;
 - (iii) environmental monitoring;
 - (iv) structure and engineering controls related to facilities;
 - (v) equipment and supplies;
 - (vi) sterile preparation calculations and terminology;
 - (vii) sterile preparation compounding documentation;
 - (viii) quality assurance procedures;
 - (ix) aseptic preparation procedures including proper gowning and gloving technique;
 - (x) handling of hazardous drugs, if applicable;
 - (xi) cleaning procedures; and
 - (xii) general conduct in the clean room.

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