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**THE BOARD OF REGISTRATION IN PHARMACY
ADVISORY ON PRE-FILLED INSULIN SYRINGES**

The Board wishes to remind registrants of the regulations regarding sterile compounding:

247 CMR 6.01(5)(c)

Any pharmacy or pharmacy department which establishes a central intravenous admixture service (CIVAS) or performs sterile compounding shall, in addition to the 300 square feet required by 247 CMR 6.01(5)(b), provide for a separate room referred to as a "clean room" apart from all other areas of the pharmacy or pharmacy department. The pharmacy shall obtain approval from the Board indicating compliance with 247 CMR 6.01 and *United States Pharmacopeia General Chapter 797* prior to initial operation of central intravenous admixture services or performance of any sterile compounding.

Sterile compounding may not be conducted at a pharmacy without a Board approved clean room pursuant to 247 CMR 6.01(5)(c). *This includes any practice related to the non-aseptic manipulation of sterile products intended for injection.* For example, **ONLY** pharmacies with an appropriate and approved clean room that upholds the standards set forth by the Board and USP <797> **may pre-fill insulin syringes for patients.**

Required Action:

If your pharmacy does not have a Board approved clean room and is engaged in the activity of manipulating sterile products, such as **pre-filling insulin syringes**, the practice must **cease immediately**. A continuity of care plan must be instituted, which may include converting patients to a commercially available pen product or transitioning the patient to an approved sterile compounding pharmacy.