Audience Response

USP 800 becomes official
a. October 1, 2019
b. November 1, 2019
c. December 1, 2019
d. January 1, 2020

Audience Response

The Massachusetts draft regulations at 247 CMR 19.0 and USP 800 are completely aligned
a. True
b. False

Audience Response

Are you ready for all the regulatory changes on the horizon?
  a. Yes
  b. No

The Imposers

- Massachusetts Board of Pharmacy
- USP
- OSHA
- NIOSH
- EPA

No conflicts to report
Massachusetts Board of Pharmacy

Draft Regulations
- 247 CMR 6.00 (Licensure of Pharmacies)
- 247 CMR 9.00 (Professional Practice Standards)
- 247 CMR 17.00 (Sterile Compounding)
- 247 CMR 19.00 (Hazardous Drug Section)

Massachusetts Board of Pharmacy

Licensure of Pharmacies – New categories
- 6.06: Application for a Sterile Compounding Pharmacy License
- 6.07: Application for a Complex Non-Sterile Compounding Pharmacy License
- 6.08: Applications for Institutional Sterile Compounding Pharmacy Licenses
- 6.15: Application for Remodeling, Change in the Configuration, or Change in Square Footage of a Pharmacy
- 6.17: Provisional Licenses

Massachusetts Board of Pharmacy

247 CMR 9.00 (Professional Practice Standards)
- 9.01 (3): Unless otherwise regulated by the Board, a licensee shall adhere to the most current standards established by each chapter of the United States Pharmacopeia ("USP").
- 9.01 (21): A pharmacist shall comply with all elements of a drug's FDA required risk evaluation and mitigation strategy ("REMS"), including any distribution or dispensing restriction included in its REMS.
- 9.04 (4): A pharmacy that provides bed-side delivery service of discharge prescriptions to patients in an inpatient healthcare facility must obtain patient consent to provide such services and may not restrict a patient's freedom of choice of pharmacy services. A pharmacy that provides bed-side delivery service shall deliver any medications directly to the patient or patient's agent.

Massachusetts Board of Pharmacy

247 CMR 9.00 (Professional Practice Standards)
- 9.04 (12): A prescription for a Schedule VI medication is valid for one year from the date of issue. A licensee may not refill a Schedule VI prescription after one year. In the event a Schedule VI prescription expires or has no remaining refills and the pharmacist is unable to obtain prescriber authorization in a timely manner, the pharmacist in his or her professional judgment may dispense a quantity not to exceed 14 days or the smallest available unit of use packaging.
- 9.08 (1): A pharmacy or pharmacist may utilize specialty compliance packaging, including oral-liquid-single-dose packaging, single-drug-single-dose packaging, and multi-drug-single-dose packaging provided the following requirements are met...

Massachusetts Board of Pharmacy

247 CMR 9.00 (Professional Practice Standards)
- 9.19 (14): A pharmacy shall maintain a written continuity of care plan that describes the manner in which patient needs will be met in the event the pharmacy is unexpectedly unable to provide pharmacy services. The pharmacy shall notify the Board if pharmacy operations are unexpectedly suspended for more than 24 hours.
- 9.19 (19): A pharmacy shall perform a self-inspection within seven days of any renovation, expansion, relocation, or change of Manager of Record, and at least one time per year, utilizing a Board-approved inspection tool for routine compliance, sterile compounding, and non-sterile compounding, as applicable. The pharmacy shall retain the completed self-inspection tool for at least two years.

Massachusetts Board of Pharmacy

247 CMR 17.00 (Sterile Compounding)
- 17.07: CSPs made with Blood-Derived or Biological Material
- 17.32: Sterile Compounding Robotics
- 17.36: Storage and Beyond-Use-Dating ("BUD")
- 17.38: Master Formulation Records (robots)
Massachusetts Board of Pharmacy

247 CMR 19.00 (Hazardous Drug Section)

• 19.02 (1) & (2): Refer to OSHA standards for MSDS & PPE
• 19.02 (5), (6) & (7): Applies to drugs on NIOSH HD list, as determined by the Board or defined by licensee

Massachusetts Board of Pharmacy

247 CMR 19.00 (Hazardous Drug Section)

• 19.03: Facility Controls
  • 19.03 (5) (a), (b) & (c): Store HDs in an externally vented negative-pressure room with at least 12 air changes per hour (ACPH). May not store HDs for sterile compounding in a negative pressure buffer room. Shall store HDs requiring refrigeration in a refrigerator dedicated to HDs and located in a negative pressure area with at least 12 ACPH.
  • 19.03 (6) & (7): Sterile and nonsterile HDs must be compounded within a C-PEC located in a containment secondary engineering control (C-SEC). A pharmacy may not compound non-sterile HDs in a negative pressure buffer room used for sterile HD compounding.

Massachusetts Board of Pharmacy

247 CMR 19.00 (Hazardous Drug Section)

• 19.06: Handling HDs
  • 19.06 (2): Personnel shall ensure that the compounding processes, handling, labeling, and transport of HDs do not introduce contamination to non-HD (handling) areas. HDs must be handled in a C-PEC during particle-generating activities (such as crushing tablets, opening capsules, and weighing powder).
  • 19.06 (7) & (8): A pharmacy shall ensure that spill kits are readily available in all areas where HDs are routinely handled.

USP 800

• December 1, 2019 official date for implementation
• Sets out practice & quality standards for compounding hazardous drugs (HDs) for healthcare personnel.
• A facility compounding HDs must incorporate USP 800 into the occupational safety plan.
  • List of HDs
  • Controls
  • Safe work practices
  • PPE
  • Waste streams
USP 800

List of HD's
- NIOSH list
- Facility's list must include any items on NIOSH list and review list annually. Facility must also add any item that meets NIOSH criteria even if not on NIOSH list.

USP 800

Personnel Handling Hazardous Drugs
- Designate a person with overall responsibility of HD compounding process
  - Overseer compliance with 800
  - Implement risk prevention policies and procedures
  - Report hazardous conditions to management
  - Monitor facility’s reports of environmental testing and sampling and act on any excursions
- All personnel are charged with understanding the HD compounding process

USP 800

Facilities and Engineering Controls
- HD Receipt
  - Receive in an area of neutral/negative pressure
- Storage
  - Store in manner that limits spillage/breakage in container falls
  - Separate from non-HD drugs
  - Negative pressure storage area with 12 ACPH
  - Refrigerated HD drugs stored in a dedicated fridge in negative pressure room with 12 ACPH. If the fridge is in the buffer room, consider exhaust located adjacent to compressor and behind if possible

USP 800

Facilities and Engineering Controls
- Containment Primary Engineering Controls (C-PEC)
  - Device designed to minimize worker exposure to HD
    - Class II BSCs barrier systems that use air to provide protection to employee, environment and drug product
      - Type A: recycle air back into buffer room
      - Type B: exhaust some or all outside of buffer room
- Containment Secondary Engineering Controls (C-SEC)
  - Room in which C-PEC is located
  - Supplemental Engineering Controls
    - Closed-system drug-transfer devices (CSTD)

USP 800

Facilities and Engineering Controls
- Sterile & non-sterile HDs must be compounded in a C-PEC located in a C-SEC
  - Externally vented
  - Appropriate ACPH
  - Negative pressure to adjacent areas
  - C-PEC must operate continuously
  - C-PEC for sterile and non-sterile should not be located in same buffer room

USP 800

Facilities and Engineering Controls
- Non-sterile HD compounding
  - Follow USP 795
  - Externally vented or redundant HEPA filters in series
  - C-PEC providing personnel and environmental protection
  - C-PEC in C-SEC with 12 ACPH
USP 800
Facilities and Engineering Controls
- Sterile HD compounding
  - Follow USP 797
  - Externally vented C-PEC
  - C-PEC providing personnel and environmental protection
  - C-PEC in C-SEC with ISO-7 buffer room environment with ISO7 ante room
    - May place C-PEC in Containment Segregated Compounding Area (C-SCA)
    - Limits BUDs
  - Negative pressure to adjacent areas

USP 800
Facilities and Engineering Controls
- Containment Supplemental Engineering Controls
  - Provide extra measure of safety
  - CSTD’s limit potential of aerosols during compounding
  - CSTD’s are not a substitute for C-PEC
  - Carefully select CSTD’s

USP 800
Environmental Quality and Control
- Wipe Sampling every six months
- No safe amount
- There are some data on levels for uptake by employees (>CTX 1ng/cm2)

USP 800
Personnel Protective Equipment (PPE)
- Covers
  - Head, face, shoes and sleeve covers
- Face and Eye
  - Goggles
- Respiratory
  - Receivers don masks
  - Spills and C-PEC cleaning
  - N95 mask
- Donning and Doffing

USP 800
Personnel Protective Equipment (PPE)
- Gloves
  - Chemotherapy gloves meet standard D6978
  - Changed every 30 minutes
- Gowns
  - Chemotherapy gowns resist permeability
  - Closed cuffs
  - Changed every 2-3 hours based on manufacturer recommendations
- Covers
  - Head, face, shoes and sleeve covers
- Face and Eye
  - Goggles

USP 800
Hazard Communication Program
- Facility SOPs to ensure effective training and periodic competency assessment for all aspects of HD handling
  - Written plan
  - Container labeling
  - MSDS (29 CFR 1910.1200)
  - Training and competency assessment
USP 800

Personnel Training
- Based upon job function
- Prior to independent performance of any HD tasks
- Annual or more competency assessment

Include:
- Facility HD list
- HD SOPs
- PPE
- Engineering controls
- Exposure and spill response
- HD disposal

USP 800

Receiving
- HDs should come to the pharmacy in impervious plastic
- PPE must be donned by receiving personnel
- HDs must be inspected for damage
  - HDs damaged in receiving process must follow spill SOPs
- Transport HDs to storage areas immediately

USP 800

Labeling, Packaging, Transport & Disposal

- Labeling
  - Clearly labeled as HD
- Packaging and Transport
  - Maintain integrity during transport
  - Protect personnel from potential exposure
  - Minimize potential leakage or breakage
  - Pneumatics tubes cannot be used
- Disposal
  - All personnel who dispose of waste must be specially trained
  - Must follow all applicable local, state and federal regulations

USP 800

Administering
- Employ protective medical devices and techniques
- Wear appropriate PPE
  - Dispose of PPE after use in in container approved for trace HD waste
- Employ CSTDs when the dosage form allows
- Administering personnel should avoid manipulating HDs

USP 800

Deactivating, Decontaminating, Cleaning & Disinfecting

- Deactivating – render inert/inactive
- Decontaminating – remove HD residue
  - Clean area with absorbent, disposable materials
  - Monthly under C-PEC work tray
  - Audit process with wipe sampling
- Cleaning – removal of contaminates
- Disinfection – Inhibit/destroy microbes from sterile compounding areas

USP 800

Spill Control
- All personnel must be specially trained
- Personnel must don PPE and respiratory protection
- Employ spill kit
- Exposed personnel/others must get immediate evaluation
USP 800

Medical Surveillance
• All personnel that regularly handle HDs should be enrolled
• Establish baseline health status and track personnel over time
• Trend personnel group data
• Develop plan for personnel who have evidence suggesting toxicity or have had an acute exposure
  • Develop plan that will limit others exposure
• Exit exam at end of worker’s employment

Audience Response

USP 800 becomes official
a. October 1, 2019
b. November 1, 2019
c. December 1, 2019
d. January 1, 2020

Audience Response

The Massachusetts draft regulations at 247 CMR 19.0 and USP 800 are completely aligned
a. True
b. False

Audience Response

Are you ready for all the regulatory changes on the horizon?
a. Yes
b. No