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Services Agency
**California Department of
Public Health**



EDMUND G. BROWN JR.
Governor

May 25, 2018

AFL 18-20

TO: General Acute Care Hospitals (GACH)

SUBJECT: New or Remodeled Pharmacy Clean Rooms and Use of Mobile Sterile Compounding Units (MSCU)

AUTHORITY: Title 22 California Code of Regulations (CCR) sections 70105, 70267, 70803, and 70805

All Facilities Letter (AFL) Summary

This AFL clarifies the California Department of Public Health (CDPH) application process for new or remodeled pharmacy clean rooms in a GACH, and the CDPH application and program flexibility request process for GACHs to temporarily use MSCUs.

On January 1, 2017, the California Board of Pharmacy updated CCR Title 16 pertaining to Sterile Compounding, including clean room requirements. Additionally, the U.S. Pharmacopeia (USP) is revising its compounding standards with an anticipated effective date of December 1, 2019. CDPH recommends facilities visit and monitor USP's website to stay apprised of developments regarding compounding requirements.

This AFL is a reminder that GACHs must obtain CDPH approval for new or remodeled pharmacy clean rooms. CDPH approval is required for all pharmacy clean rooms under the hospital's license, including projects the Office of Statewide Health Planning and Development (OSHPD) identifies as subject to Title 24, California Building Standards Code for licensed clinics ("OSHPD 3"). For example, a GACH must apply for CDPH approval for a new or remodeled clean room in an infusion clinic that operates under the GACH's license.

GACHs opting to temporarily use a MSCU to provide pharmaceutical services during the construction or remodel of pharmacy clean rooms must obtain CDPH approval. The CDPH application process for using a MSCU includes obtaining a program flexibility approval. CDPH Licensing and Certification (L&C) Program has the authority to grant program flexibility from regulatory requirements as long as the facility meets statutory requirements.

Pharmacy clean room and MSCU projects involve multiple state entities, including OSHPD, the California Board of Pharmacy, and CDPH. CDPH recommends that hospitals plan ahead to allow sufficient time to obtain all required approvals.

CDPH Application Process for New or Remodeled Pharmacy Clean Rooms

Facilities seeking approval for a new clean room must:

1. Apply for CDPH approval by submitting the required forms to the Centralized Applications Unit (CAU). The application requirements are located on the General Acute Care Hospital Pharmacy Clean Room and Sterile Compounding Applicant Check List.
 - CDPH recommends facilities apply 120 days prior to the new pharmacy clean room's anticipated construction completion date.
 - Submit documents via mail to:
California Department of Public Health
Centralized Applications Unit
Attn: Licensing and Certification Program
Pharmacy Clean Room and Sterile Compounding Projects
PO Box 997377, MS 3207
Sacramento, CA 95899-7377
2. Contact the CDPH Pharmaceutical Consultant Unit (PCU) to initiate the administrative review of the clean room, by emailing: LNCPharmCleanRoom@cdph.ca.gov.
 - CDPH recommends contacting PCU 90 days prior to the anticipated construction completion date.
 - To expedite the CDPH administrative review of the new clean room, please review the Examples of Documentation.

CDPH Application Process for the Use of MSCUs

Facilities seeking approval for the temporary use of a MSCU must:

1. Apply for CDPH approval for the temporary use of a MSCU by submitting the required forms to CAU. The application requirements are located on the General Acute Care Hospital Pharmacy Clean Room and Sterile Compounding Applicant Check List.
 - CDPH recommends applying for approval of a MSCU 120 days prior to the date of intended use.
 - Submit documents via mail to:
California Department of Public Health
Centralized Applications Unit
Attn: Licensing and Certification Program
Pharmacy Clean Room and Sterile Compounding Projects
PO Box 997377, MS 3207
Sacramento, CA 95899-7377
2. Apply for a program flexibility by submitting a Program Flexibility Request form to the appropriate District Office (DO). Requests for program flexibility must include justification for the flexibility request and adequate supporting documentation that the proposed alternative does not compromise patient care. CDPH reviews requests for program flexibility on a case-by-case basis.
 - CDPH recommends submitting the program flexibility request concurrently with CAU MSCU documents, 120 days prior to the date of intended use.
 - The CDPH review process for a MSCU program flexibility request includes an administrative review by the PCU.
 - If you have any questions regarding program flexibility requests, please contact your local DO.

To facilitate the MSCU application process, CDPH requests that GACHs contact PCU prior to the delivery of the MSCU to the GACH by emailing: LNCPharmCleanRoom@cdph.ca.gov.

For questions regarding this AFL, please contact the Centralized Applications Unit by email at CAU@cdph.ca.gov or by telephone at (916) 552-8632.

Sincerely,

Original signed by Jean Iacino

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Deputy Director

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