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California Department of Public Health



GAVIN NEWSOM
Governor

May 13, 2019

AFL 19-19

TO: General Acute Care Hospitals (GACH)

SUBJECT: New or Remodeled Pharmacy Clean Rooms and Use of Mobile Sterile Compounding Units (MSCU)
Supersedes AFL 18-20

AUTHORITY: Title 22 California Code of Regulations (CCR) sections [70105](#), [70267](#), [70803](#), and [70805](#). Health and Safety Code (HSC) section [1272](#)

All Facilities Letter (AFL) Summary

This AFL supersedes AFL 18-20 to update the California Department of Public Health's application submission process and recommended timelines for:

- New or remodeled pharmacy clean rooms
- Temporary use of MSCUs

AFL 18-20 detailed the application process for GACHs applying for new or remodeled pharmacy clean rooms and MSCUs. CDPH has updated the application process and timelines as a result of the enactment of Assembly Bill 2798 (Chapter 922, Statutes 2018), that imposes new processing times for hospital applications submitted to CDPH. CDPH must now review and approve or deny a written application submitted by a GACH, within 100 days of receipt, including all related activities. To meet this requirement, CDPH will not accept or process applications for pharmacy clean rooms or MSCUs until CDPH has received all of the required application documents, including:

- California Board of Pharmacy Sterile Compounding License
- Office of Statewide Health Planning and Development (OSHPD) Certificate of Occupancy

On January 1, 2017, the California Board of Pharmacy updated Title 16 CCR 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

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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 an approved program flexibility and CDPH approval for the MSCU by submitting an application to the Centralized Applications Branch (CAB). 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 CAB. The application requirements are located on the [General Acute Care Hospital Pharmacy Clean Room and Sterile Compounding Applicant Check List](#).
 - CDPH recommends facilities apply after obtaining all of the required application documents.
 - Submit documents via mail to:
California Department of Public Health
Licensing and Certification Program
Centralized Applications Branch
Attn: 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.
 - To expedite the CDPH administrative review of the new clean room, please review the [Examples of Documentation](#).

To facilitate the new/remodeled clean room application process, CDPH recommends that GACHs contact PCU 120 days prior to the new pharmacy clean room's anticipated construction completion date by emailing: LNCPharmCleanRoom@cdph.ca.gov.

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 CAB. The application requirements are located on the [General](#)

[Acute Care Hospital Pharmacy Clean Room and Sterile Compounding Applicant Check List.](#)

- CDPH recommends facilities apply after obtaining all of the required application documents.
 - Submit documents via mail to:
California Department of Public Health
Licensing and certification Program
Centralized Applications Branch
Attn: 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.
- 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 Branch by email at CAB@cdph.ca.gov or by telephone at (916) 552-8632.

Sincerely,

Original signed by Heidi W. Steinecker

Heidi W. Steinecker
Deputy Director