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California Department of Public Health

EDMUND G. BROWN JR.
Governor

February 3, 2017

AFL 17-05

TO: Intermediate Care Facility
Nursing Facilities
Skilled Nursing Facilities

SUBJECT: Senate Bill (SB) 1193: Healing Arts (Chapter 484, Statutes of 2016)

All Facilities Letter (AFL) Summary

- This AFL notifies providers of the chaptering of SB 1193, that effective January 1, 2017, reinstates skilled nursing facilities' (SNF), nursing facilities' (NF), and intermediate care facilities' (ICF) ability to use automated drug delivery systems (ADDS) that allow personnel to have access to multiple drugs not patient specific in their design if those systems have electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient.
- Facilities must obtain authorization from the California Department of Public Health's Licensing and Certification Program (L&C) prior to using an ADDS that meets the aforementioned criteria.

Prior to January 1, 2012, HSC section 1261.6 permitted SNF, NF, and ICF personnel to access multiple drugs that are not patient specific only if an ADDS had both electronic and mechanical safeguards in place to ensure that the only drugs delivered to the patient were specific to that patient. This was initially a pilot program that sunsetted January 1, 2012. SB 1193 repeals the sunset provision, thereby reauthorizing the use of these devices in SNFs, NFs, and ICFs provided they meet all requirements.

This AFL notifies providers that effective January 1, 2017, SB 1193: Healing Arts reinstates SNFs, NFs, and ICFs ability to use ADDS that allow personnel to have access to multiple drugs not patient specific in their design if those systems have electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient.

Obtaining L&C Authorization to Use an ADDS Not Patient Specific in Design pursuant to Health and Safety Code (HSC) section 1261.6

Pursuant to HSC section 1261.6, facilities choosing to install an ADDS that allows personnel to have access to multiple drugs not patient specific in their design must complete the following steps to maintain compliance with ADDS statutory requirements:

- Notify L&C in writing prior to using the system.
- The notification submitted to the department must include, but is not limited to, information regarding system design, manufacturer make/model number (where applicable), personnel with system access, and policies and procedures covering staff training, storage, security, and the facility's administration (intended use) of these types of systems.
- Submit the notification and all supporting documentation electronically to CDPH's L&C Program at:

LNC-PHARM-Consult@cdph.ca.gov

If…	Then…

The facility submits all required documentation	L&C will send an authorization letter to the facility acknowledging receipt of the notification and all required supporting documentation to permit use.
The facility fails to submit all required documentation	L&C will send a denial letter including the reason(s) for the denial.

During the course of any L&C survey process, L&C will review a facility's medication training, storage, security, and administration procedures related to its use of an ADDS that is not patient specific in its design. These surveys will confirm that adequate staff training and safeguards are in place to ensure the health and safety of the patient.

If L&C determines that a facility is not in compliance with HSC section 1261.6, L&C will revoke the facility's authorization to use any ADDS not patient specific in its design and make a referral to the Board of Pharmacy (BOP) regarding their non-compliance with the requirements set forth in HSC section 1261.6.

Examples of an ADDS not patient specific in design include, but are not limited to:

- ADDS containing multiple medications, packaged in individual, non-patient specific bubble/blister cards, stored in a drawer without mechanical barriers to access, such as electronically controlled lids.
- ADDS with matrix cell drawers not covered with electronically controlled lids.

Please note that L&C's responsibility is limited to authorizing the use of an ADDS not patient specific in its design as an integral part of the facility's pharmaceutical service as detailed by HSC section 1261.6. L&C's authorization does not extend to an approval of the installation or ongoing maintenance of the device or a validation of compliance with any other requirements pertaining to the device or its use.

ADDS Licensure

Pursuant to Business and Professions Code (BPC) section 4119.1, any pharmacy that owns or operates an ADDS of any make or model must maintain compliance with requirements set forth in HSC section 1261.6.

Furthermore, BPC section 4105.5 requires any pharmacy to register the device with the BOP within 30 days of installation and on an annual basis as part of the ADDS license renewal. The pharmacy must also notify the BOP in writing within 30 days if the pharmacy discontinues operating a licensed ADDS.
Please contact the BOP for more information regarding registration requirements. The board's website may be accessed at:

California State Board of Pharmacy: http://www.pharmacy.ca.gov/

This AFL is a brief summary of the changes that SB 1193 makes to the Health and Safety Code. Facilities are responsible for following all applicable laws. CDPH's failure to expressly notify facilities of statutory or regulatory requirements does not relieve facilities of their responsibility for following all laws and regulations. Facilities should refer to the full text of all applicable sections of the Health and Safety Code and Title 22 of the California Code of Regulations to ensure compliance.

Sincerely,

Original signed by Jean Iacino

Jean Iacino
Deputy Director

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