California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Organizational Development Committee

Gregory Lippe, Public Member, Board Vice President (Acting President)

a. Budget Report/Update

Fiscal Year 2017/2018

The Chief of Fiscal Operations for DCA released a memo in April 2019 regarding the FI$CAL system and the delay in the final 2017/18 year-end budget information. As indicated in the memo, due to challenges in the reconciliation and closing of fiscal year 2017/18, the year-end statistics will not be available until after June 2019.

Board staff recently received an update from DCA Fiscal Operations that FY 2017/18 year-end budget information should be available August 2019. **Attachment 1** contains a copy of the April 2019 memo.

Fiscal Year 2018/2019

On June 28, 2018, the Governor signed the budget for FY 2019/20. The new budget year began July 1, 2019. The board's spending authorization for the year is $26,007,000, which is an 11.3% increase from the prior year.

As previously noted there continues to be a delay in receiving budget information due to the problems with the FI$CAL accounting system. Based on the preliminary reporting the board believes it has received $25,582,100 in revenue originating from the following:

Revenue Sources Table

Source	Amount	Percentage
Licensing	$23,446,900	92%
Citation Fines	$1,056,300	4%
Cost Recovery	$872,400	3%
Interest	$206,500	1%

Further, the board has expended $20,267,900 through May 2019. The largest expenditure categories are detailed below.

Expenditures Table

Source	Amount	Percentage
Personnel	$14,552,500	72%
Enforcement	$3,695,000	18%
Prorata	$508,200	3%

Below is a summary of the fund condition report prepared by the department with the available budget reports. The fund condition assumes that the new fees will be in place no later than July 1, 2020.

Fund Condition Table

Fiscal Year	Fund Balance	Months in Reserve
2017/2018	$8,614,000	3.7
2018/2019	$4,444,000	1.9
2019/2020	$829,000	0.4
2020/2021	$5,513,000	2.3
2021/2022	9,728,000	4.0

Attachment 1 includes the fund condition prepared by the department and detailed budget charts.

b. Board Member Attendance Information

Attachment 2 includes a summary of board member attendance at committee and board meetings this fiscal year.

c. Discussion and Consideration of Committee Meetings and Board Meetings for Fiscal Year 2019/20

Attachment 3 includes the committee and board meeting locations for FY 2019/20. Where locations have been identified, such information is provided as well. The schedule reflects the action from the last board meeting wherein the board will be consolidating some board and committee meetings.

d. Discussion and Consideration of Designating all or Portions of the decision, *In the Matter of the Citation Against Omnicare, Inc., Omnicare Holding Co., dba Omnicare of Cerritos, Case No CI 2014 63230, OAH case number 2017070407* as Precedential Pursuant to Government Code Section 11425.6

Staff recommends the board's action to adopt as a precedential decision the Omnicare of Cerritos (Omnicare) matter. Omnicare is licensed with the board as a pharmacy.

As indicated in the memo, the board issued a citation to Omnicare for violations of California pharmacy law, specifically California Code of Regulations, title 16, Section 1793.7. As detailed in the memo from counsel, the cited violation was based on an inspector's alleged observation that, on May 2, 2016, three pharmacists were supervising nine pharmacy technicians as they performed their licensed job duties, in violation of the regulation requiring a ratio of at least one pharmacist on duty for every two pharmacy technicians on duty.

Although there were seven pharmacists on duty on the date of the inspection, only three were engaged in direct supervision of technicians. The other pharmacists were not counted towards the ratio, as they were on site in a separate room, which afforded no view of the pharmacy area and no opportunity for direct oversight of technicians. The Decision found that although the other four pharmacists may have been generally aware that there were technicians in the pharmacy, performing licensed tasks, that awareness was not direct supervision. Making this case precedential decision would clarify that general awareness of pharmacy technicians performing licensee tasks is not sufficient to meet the standard imposed by the board's regulation.

Provided in **Attachment 4** is a memo from DCA counsel Kelsey Pruden providing more detail on the matter as well as the decision.

Should the board agree with the staff's recommendation, the following motion could be used.

Suggested Motion: Adopt as precedential the decision in the *In the Matter of the Citation Against Omnicare, Inc., Omnicare Holding Co., dba Omnicare of Cerritos, Case No CI 2014 63230, OAH case number 2017070407*.

e. Update on Implementation of the Acceptance of Credit Cards for Renewal Payments

On December 17, 2018, the board implemented the online credit card renewal payment process for pharmacy technicians. Between December 17, 2018, and June 30, 2019, the board received 5,256 pharmacy technician renewal payments through the credit card process.

On February 27, 2019, the board implemented the online credit card renewal payment process for pharmacists (including advanced practice pharmacists). Between February 27th and June 30, 2019, the board received 1,678 pharmacist renewal payments and 7 advanced practice pharmacist renewal payments through the credit card process.

On June 4, 2019, the board implemented the online credit card renewal payment process for designated representatives. Between June 4th and June 30, 2019, the board received 7 designated representative renewal payments through the credit card process.

During April, May, and June, the percentage of renewals that were paid online each month (versus via mail) are as follows:

- April 26%
- May 37%
- June 39%

f. Sunset Report Update

Attachment 5

As previously discussed, about every four years the board undergoes the Sunset Review Process. As a precursor to the process, the board is typically asked to prepare a report. Although the board has not received its formal notice requesting preparation of the report, staff believes it will be forthcoming. It is anticipated that the report will be due the end of the year.

The preparation of the report takes several months and is an opportunity to provide information for the legislative oversight committees to learn about the board's achievements related to its mission.

Currently board staff is preparing various datasets that it believes will be required as part of the reporting elements of the report. The data will also provide some of the context from which the board can highlights its achievement.

As the board prepares to undergo the process, the board's strategic committees may wish to consider possible issues to highlight during the sunset process.

During the board's last discussion on this topic it was determined that board staff will work with the board's president and vice president on development of the report and once completed, the report will be provided to all board members for review and approval, which is expected late in 2019.

Attachment 5 includes a timeline of the Sunset Review process provided by DCA.

g. Personnel Update

The board currently has eight vacant positions detailed below.

- Executive Officer
- Two Inspector positions
- One Licensing position
- Two Enforcement positions
- Two Administrative positions

h. Update on the Relocation of Board Office

The relocation of the board's office was completed over the last weekend in June 2019. Board services were limited on June 28 and July 1 but resumed July 2. Staff are working diligently to reduce delays caused by the move.

i. Update on Implementation of SB 1447 (Chapter 666, Statutes of 2018) Pharmacy: automated drug delivery systems.

Attachment 6

SB 1447 ADDS provisions took effect July 1. Built in to the legislation was a delay in the implementation as typically legislation becomes effective January 1.

Discussions on the legislation occurred at the committee and board level. In December 2018, the Enforcement Committee discussed this measure. In addition, the Licensing Committee reviewed and recommended approval of the draft self-assessment form. That form was subsequently approved by the board for promulgation.

It was anticipated that this topic would again be discussed during the June Licensing Committee Meeting, that regrettably was cancelled.

To mitigate impact to patients, board staff started performing inspections in advance of the July 1 implementation date using information from the board's previous registration requirements. Unfortunately, as staff moved forward with implementation, several challenges with regulatory compliance became apparent. To ensure continuity of patient care, and with the approval of the board's president and vice president, a subscriber alert was released providing an extension for compliance with the new licensing requirements.

Staff continues its efforts to secure compliance and issue licenses. To date the board has issued 259 ADDS licenses.

Attachment 6 includes a copy of the subscriber alert and draft FAQ's.

j. Report of Multi-Year Comparisons of Licensing and Enforcement Statistics

Attachment 7

Attachment 7 includes multi-year comparisons for licensing statistics.

As indicated in the licensing statistics, the board's licensee population remains relatively flat, with the most growth noted as a result of new licensing programs. There was a five percent increase noted in the board's pharmacist licensee population as well as 429 percent increase in the number of advance practice pharmacists.

The number of applications received overall declined about three percent, however the number of pharmacist applications increased by eight percent as well as large increases in clinic applications. Pharmacy applications dropped about 56 percent, however this number is easily impacted when large buyouts occur.

Trends along with the enforcement statistics will be provided during the meeting.

Attachment 1

A hardcopy of these documents will be made available upon request.
Requests may be emailed to debbie.damoth@dca.ca.gov.

Attachment 2

Full Board Meetings – FY 2018/2019

	7/ 24/18	7/25/18	9/7/2018	9/26/2018	10/23/18	10/24/18	12/14/18
Brooks			x		x	x	
Butler	x	x		x	x	x	
Khan			x				
Kim	x	x			x	x	x
Law	x	x	x	x	x	x	x
Lippe	x	x	x		x	x	x
Munoz				x		x	
Sanchez	x	x	x	x	x	x	x
Schaad	x	x			x	x	x
Serpa	x	x	x	x	x	x	x
Veale	x	x		x	x	x	x
Weisser	x	x	x	x			x
Wong	x	x	x	x	x	x	x

	1/30/19	1/31/19	3/22/19	4/16/19	5/7/19	5/8/19	6/21/19
Brooks	x	x					x
Butler	x	x	x	x	x	x	x
Khan							x
Kim			x				
Law	x	x	x	x	x	x	x
Lippe	x	x	x	x	x	x	x
Munoz				x	x		
Sanchez	x	x	x	x	x	x	x
Schaad	x	x			x	x	x
Serpa	x	x	x	x	x	x	x
Veale	x	x	x	x	x	x	
Weisser	x	x	x	x	x		
Wong	x	x	x		x	x	x

Enforcement Committee Meetings – FY 2018/2019

	September 14, 2018	December 20, 2018	March 14, 2019
Law	x	x	x
Lippe	x		x
Sanchez	x	x	x
Schaad	x	x	x
Weisser	x	x	x
Wong	x	x	x

Compounding Committee Meetings – FY 2018/2019

	February 20, 2019	March 13, 2019	April 16, 2019	June 4, 2019
Kim				
Law	x	x	x	x
Schaad	x	x	x	x
Serpa	x	x	x	x
Weisser		x	x	

Legislation and Regulation Committee Meetings – FY 2018/2019

	July 24, 2018	October 23, 2018	January 30, 2019	May 7, 2019
Brooks		x	x	
Butler	x	x	x	x
Khan				
Lippe	x	x	x	x
Serpa	x	x	x	x

Licensing Committee Meetings – FY 2018/2019

	September 26, 2018	**December 19, 2018**	**April 3, 2019**
Butler	x	x	x
Khan			
Schaad		x	x
Veale	x	x	x
Weisser	x	x	
Wong	x	x	x

Communication and Public Education Committee Meetings – FY 2018/2019

	October 11, 2018	**January 8, 2019**	**May 7, 2019**
Brooks		x	
Kim		x	
Munoz	x		x
Sanchez	x	x	x
Veale	x	x	x

Attachment 3

Committee and Board Meeting Locations FY 2019/20 and Partial FY 2020/21

Date	Type of Meeting	Location
Jul. 24-25, 2019	Committee and Board Meeting	Embassy Suites Anaheim North, Anaheim, CA
Aug. 28, 2019	Compounding Committee Meeting	USC Orange County Center Irvine, CA
Sept. 13, 2019	Petitioner Board Meeting	Board of Pharmacy Sacramento, CA
Sept. 24, 2019	Compounding Committee Meeting	Board of Pharmacy Sacramento, CA
Sept. 25, 2019	Enforcement Committee Meeting	Board of Pharmacy Sacramento, CA
Oct. 16, 2019	Compounding Committee Meeting	USC Orange County Center Irvine, CA
Nov. 5-6, 2019	Committee and Board Meeting	Contract Pending San Diego, CA
Dec. 13, 2019	Petitioner Board Meeting	Chapman University Irvine, CA
Jan. 29-30, 2020	Committee and Board Meeting	KGI School of Pharmacy Claremont, CA
Mar. 13, 2020	Petitioner Meeting	Board of Pharmacy Sacramento, CA
May 5-6, 2020	Committee and Board Meeting	Department of Consumer Affairs Sacramento, CA
Jun. 19, 2020	Petitioner Meeting	*TBD Southern California*
Jul. 8, 2020	Licensing, and Communication & Public Education Committee Meetings	*TBD*
Jul. 9, 2020	Enforcement, and Legislation & Regulation Committee Meetings	*TBD*
Jul. 29-30, 2020	Board Meeting*	*TBD*
Sept. 25, 2020	Petitioner Meeting	*TBD*
Oct. 27-28, 2020	Committee and Board Meeting	*TBD*
Dec. 4, 2020	Petition Meeting	*TBD*

*****Under the approved proposal, committees will convene one standalone meeting a year to set the strategic and policy objectives for the year. I suggest that this occur in advance of the July Board Meeting.

Attachment 4

A hardcopy of these documents will be made available upon request.
Requests may be emailed to debbie.damoth@dca.ca.gov.

Attachment 5

A hardcopy of these documents will be made available upon request.
Requests may be emailed to debbie.damoth@dca.ca.gov.

Attachment 6

Damoth, Debbie@DCA

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV> on behalf of California State Board of Pharmacy <00000005e0d26dcf-dmarc-request@SUBSCRIBE.DCALISTS.CA.GOV>
Sent: Monday, June 24, 2019 3:16 PM
To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV
Subject: Licensure of Automated Drug Delivery System (ADDS) Devices

As the board continues its implementation on SB 1447, the board strongly recommends all facilities that currently use an Automated Drug Delivery System (ADDS) read this message and take any necessary steps to come into compliance with existing and new laws.

The board thanks the pharmacists-in-charge of the pharmacies that have worked with board inspectors to arrange inspections at the various locations, as well as those entities that have submitted applications to secure licensure of each system.

Regrettably, based on the applications submitted, it does not appear that licensure of all ADDS will be achieved by July 1, 2019, as required by the law. The causes are many, but the board would like to highlight some of the common challenges encountered when fulfilling licensing requirements.

- Not all currently used ADDS were registered with the board under prior legal requirements and therefore did not receive the board's courtesy notices about the new requirements. If you are currently operating an ADDS, even if you had not previously registered it, please review the law to determine if you must obtain a license pursuant to Business and Professions Code sections 4427 – 4427.8 or Article 25 of Pharmacy Law. Except for certain hospital pharmacies using an ADDS solely for hospital staff to administer medication to its patients, all ADDS must be licensed. Unless you are certain you are exempt, the board encourages you to email ADDS@dca.ca.gov to request an inspection. Please include in the Subject Line of the email "ADDS Inspection Request" with the pharmacy license number; in the body of the email, please include the name of the pharmacy, name and email contact information of the PIC, and location of the ADDS device. Further, please download the application form and submit the application, required documents, and fees as soon as possible to ensure the facility is in compliance with the new requirements effective July 1, 2019. The application can be found using the following link: https://www.pharmacy.ca.gov/forms/adds_app.pdf

- Upon receipt of ADDS applications, the board is identifying PIC and officer changes that have not been previously reported to the board, which is required by law under separate provisions. If such a situation applies to your facility, to assist in the processing of the ADDS application, please download the appropriate application to report management changes and submit the application, required documents, and fees as soon as possible but no later than July 1, 2019. The board requests that you submit a cover letter with such applications indicating that an ADDS application is also pending with the board. Applications to report management changes can be found using the following link: https://www.pharmacy.ca.gov/licensees/facility/facility_lic_info.shtml

- Not all required documentation is being submitted with the applications. For example, for nursing facilities, please ensure that a copy of the CDPH license is provided and that the location of the ADDS is consistent with the name and location listed on the CDPH license.

Upon issuance of an ADDS license, the PIC will receive an email notification of approval. Until the license is received, a copy of the email notification can be posted on the device.

Given the current deficiencies, the board will allow currently registered ADDS operating pursuant to Health and Safety Code section 1261.6 to continue operating under an existing registration until July 31, 2019.

###

Automated Drug Dispensing Systems (ADDS)

FREQUENTLY ASKED QUESTIONS:

Licensing Process:

1. **QUESTION:** Our pharmacy will be discontinuing the use of an ADDS at a skilled nursing facility that was registered with the Board. How do I notify the Board of the discontinuance of the ADDS?

   ANSWER: A pharmacy is required to notify the Board in writing of the discontinuance of the ADDS within 30 days of the discontinuance. You may use the form that will be posted on the Board's website. Until the form is available, the pharmacy may also submit in writing to the Board, ideally with the following information:
   - Name and license number of the retail pharmacy, hospital pharmacy, licensed correctional facility pharmacy, or clinic;
   - Name, phone number, and email of the contact person at the retail pharmacy, hospital pharmacy, licensed correctional facility pharmacy or clinic;
   - Address and location of the ADDS, including location's name;
   - ADDS registration number and type of ADDS; and
   - Date the ADDS was discontinued.

   Reference: BPC 4427.2(g)

2. **QUESTION:** Where will the license for the ADDS location be mailed?

   ANSWER: The license for the ADDS will be mailed to address of record for the pharmacy that obtained the ADDS license.

   Reference: BPC 4427.2(a), (b).

3. **QUESTION:** When I receive my license where do I post the ADDS license, at the pharmacy or at the location of the ADDS?

   ANSWER: The pharmacy will be required to display the original license and current renewal license for an ADDS at the licensed ADDS location in a place where it may be clearly read by the public.

4. **QUESTION:** Can the Board coordinate the expiration date of the ADDS license with the pharmacy's license expiration date?

   ANSWER: Yes. The ADDS license will be renewed annually, and the renewal date will be the same as the underlying pharmacy license.

   Reference: BPC 4427.2(h)

5. **QUESTION:** We are a government owned pharmacy. Are we required to pay the $200 application fee to license an ADDS?

   ANSWER: Yes. Business and Professions Code section 4400(aa) is not limited to nongovernmental ADDS. Therefore, the $200 application fee applies to all ADDS licensed by the Board.

   Reference: BPC 4400(aa)

6. **QUESTION:** We have two ADDS located in the same medication room at a skilled nursing facility. Can we pay $200 to license both ADDS since they are located at the same location?

   ANSWER: No. Each ADDS is required to be licensed separately and the $200 application fee applies to each ADDS. Therefore, to license both systems, you will need to submit a payment of $400 (2 ADDS x $200 per ADDS = $400).

   Reference: BPC 4427.2(c)

7. **QUESTION**: If a pharmacy wants to add a tower to an existing ADDS to expand the size of the existing ADDS for additional storage and for oversized drug products, is the pharmacy required to submit an application for a new ADDS license?

   ANSWER: No, a new ADDS application for licensure is not required, as long as the existing ADDS remains at the location that was licensed. However, if the original ADDS that was licensed is replaced with a different ADDS with a tower, then the pharmacy license holder of the ADDS is required to notify the board within 30 days.

   Reference: BPC 442.7.2(e)

8. **QUESTION**: If a pharmacy transfers its ADDS restocking and other functions to another pharmacy under the same ownership, must the owner obtain a new license for the ADDS?

   ANSWER: Yes. The pharmacy licensed to operate the ADDS must notify the board of the discontinuance of the ADDS and the other pharmacy, the one stocking and operating the ADDS, must apply for a new license. Each ADDS can only be operated under the supervision of one pharmacy holding the ADDS license. The drugs and devices stored in an ADDS are considered to be part of the inventory and the responsibility of the pharmacy holding the ADDS license and the drugs and devices dispensed from the ADDS are considered to be dispensed by the pharmacy. Therefore, the pharmacy that is the original holder of the ADDS license must advise the board in writing within 30 days when the pharmacy discontinues the use of the ADDS. The pharmacy under that will be operating and restocking the ADDS must apply for license the ADDS license.

   Reference: BPC 4427.2(a)(c)(e), 4427.7

9. **QUESTION**: If an ADDS is replaced with a newer model, what is the process?

   ANSWER: As long as the location and pharmacy operating the ADDS is the same, the pharmacy must only notify the board within 30 days. The board has a form the pharmacy may use to provide notice of the replacement of an ADDS on its website (www.pharmacy.ca.gov).

   Reference: BPC 4427.2(e)

10. **QUESTION**: During the prelicensure inspection of the ADDS location, the inspector noticed the room where the ADDS was located was very warm. Is the pharmacy required to maintain proper storage of the drugs within the ADDS or at location where the ADDS is installed?

    ANSWER: The pharmacy is responsible for storing dangerous drugs and devices in a manner, so they do not become adulterated, regardless of where they are stored, and that includes the ADDS and, if it could affect the proper storage, the location where the ADDS is installed. Prior to installation, the pharmacy submitting the application for an ADDS license and any facility where the ADDS will be located must jointly develop and implement written policies and procedures to ensure the maintenance of the ADDS, as well as to maintain the quality, potency, and purity of the drugs and devices stored in the ADDS. Drugs in the ADDS that are not properly stored according to the manufacturer's recommended temperatures may be considered adulterated, and the pharmacy may not be able to authorize their use. As a result, the board recommends the policies and procedures address storage conditions, including who is responsible for monitoring the temperature of the room and/or the storage conditions of the drugs or devices in the ADDS, which conditions and how those conditions will be measured, and the frequency with which measuring will occur. The board does not establish particular storage or monitoring conditions for pharmacies to apply because the appropriate conditions will vary depending on things like the type of ADDS, the specific drugs being stored, etc. The pharmacy's PIC should exercise his or her professional judgment to determine if the policies and procedures ensure that the drugs that will be placed in the ADDS have been stored appropriately.

    Reference: BPC 4119.01, 4169(a)(2), 4186, 4187.5, 4427.3(c); HSC 111250 et seq.

11. **QUESTION**: I submitted my application for an ADDS and have completed the pre-licensure inspection. How will I know my application has been approved before I receive the physical license to be posted?

    ANSWER: Once the application is approved, an email will be sent to the pharmacist-in-charge (PIC). The email will notify the pharmacy the application was approved and will include the ADDS license number, type of ADDS, the primary pharmacy license, the status, the name and address of the ADDS location, and expiration date. The board requests that you print and attach a copy of the email to the location of the ADDS and replace when the original is received. Allow 4 to 6 weeks to receive the physical license in the mail at the pharmacy.

12. **QUESTION**: Will I be able to look up on the board's website an ADDS license?

    ANSWER: No. ADDS licenses are not currently searchable on the board's web site.

Retail Pharmacy:

13. **QUESTION**: Our pharmacy uses an ADDS that labels and dispenses medications for the pharmacy. Before it gets dispensed to the patient, it passes through a quality check from a pharmacist. Would this qualify as an ADDS requiring the pharmacy to obtain a license?

    ANSWER: No, the pharmacy does not require the ADDS used in the pharmacy to be licensed. An ADDS license is not required for technology, installed within the secured licensed premises area of a pharmacy, used in selecting, counting, packaging, and labeling of dangerous drugs and dangerous devices.

    Reference: BPC 4427.2(j)

LTC Pharmacy

14. **QUESTION:** If an ADDS was already installed at a skilled nursing facility and registered pursuant to former BPC 4105.5, does it require a pre-licensure inspection?

    ANSWER: Yes, all applications for licensing an ADDS require an inspection. The board will inspect the proposed installation location within 30 days of a completed application for an ADDS.

    Reference: BPC 4427.2(e)

Hospital Pharmacy:

15. **QUESTION:** We are a licensed acute care hospital pharmacy that oversees the ADDS at the nursing stations throughout the hospital. The drugs are used for administration only. The nurses will access the ADDS to remove drugs pursuant to a physician order. Are we required to license each ADDS?

    ANSWER: No. An ADDS used as an automated unit dose system (AUDS) operated by a licensed hospital pharmacy, as defined in BPC section 4029, and used solely to provide doses administered to patients while in a licensed general acute care hospital facility or a licensed acute psychiatric hospital facility, as defined in subdivisions (a) and (b) of Section 1250 of the Health and Safety Code, is exempt from the requirement of obtaining an ADDS license if the licensed hospital pharmacy owns or leases the AUDS and owns the dangerous drugs and dangerous devices in the AUDS. The AUDS must, however, comply with all other requirements for an ADDS. The licensed hospital pharmacy must maintain a list of the locations of each AUDS it operates and must make the list available to the board upon request.

    Reference: BPC 4017.3, 4029, 4427.2(i)

16. **QUESTION**: We are an acute care hospital with 20 skilled nursing beds in a distinct part listed on the hospital's license issued by the California Department of Public Health with ADDS used for administration only. Are we required to license the ADDS used as AUDS for the 20 skilled nursing beds in the distinct part?

    ANSWER: The answer depends on who owns or lease the ADDS and the drugs stocked in the ADDS.

    - If the licensed hospital's pharmacy uses the ADDS solely to provide doses administered to patients, owns or leases the AUDS, and owns the dangerous drugs and dangerous devices in the AUDS, then the licensed hospital pharmacy is not required to obtain a license for the AUDS.
    - If a pharmacy other than the licensed hospital pharmacy owns or leases the AUDS and own the dangerous drugs and dangerous devices in the AUDS, then the pharmacy is required to obtain a license for the AUDS.

    Reference: BPC 4427.2(i)

17. **QUESTION**: We are an acute care hospital pharmacy that operates ADDSs located in clinics that are used for administration only. Are we required to license each of the ADDS in the clinics?

    ANSWER: The answer depends on whether the clinics with the ADDS are listed on the acute care hospital license issued by the California Department of Public Health.

    - If the clinic is listed on the acute care hospital license as an approved service and the ADDS is used as an AUDS for administration of dangerous drugs and dangerous devices to patients of the clinic, then the acute care hospital pharmacy is not required to license the ADDS.
    - If the clinic is not listed on the acute care hospital license as an approved service, then the acute care hospital pharmacy is required to license each ADDS located at the clinic. An ADDS can be placed in a clinic licensed pursuant to Section 1204 or 1204.1 of the Health and Safety Code, or Section 4180 or 4190 of the Business and Professions Code

    Reference: BPC 4427.2(i), BPC 4427.3(b)(3)

18. **QUESTION**: We are an acute care hospital pharmacy that would like to place an APDS in physician offices where patients are regularly seen for purposes of diagnosis and treatment. Is the hospital pharmacy exempt from licensing the APDS?

    ANSWER: No, the hospital pharmacy is not exempt and a license for the APDS location will be required. The exemption only applies to ADDS used solely to provide doses administered to patients while in a licensed general acute hospital facility or licensed acute psychiatric hospital facility.

    Reference: BPC 4427.2(i)

19. **QUESTION**: We are a hospital with less than 100-beds and have a licensed "drug room" pursuant to BPC 4056. When patients are discharged from the hospital, the physician sometimes writes an order for the patient to be discharged with a 72-hour supply, which is dispensed from the ADDS. The physician will remove the drugs from the ADDS and dispense the drugs to the patient that is properly labeled and meets the patient centered labeling requirements. Is the ADDS located at the nursing station exempt from licensure if it is primarily used to administer doses to patients in the hospital, but occasionally used for dispensing no more than a 72-hour supply of discharge medications to the patient?

    ANSWER: No, the ADDS is not exempt. The drug room will be required to obtain a license for the ADDS. The drug room is only exempt if the drugs in the ADDS are solely used for administration to patient while in the acute care hospital. When drugs from the ADDS are used for dispensing, not solely for administration, the exemption no longer applies.

    While the ADDS must be licensed, as long as the physician removes the dangerous drug or device from the ADDS to dispense to the patient, the ADDS is not considered to be an APDS and need not follow the APDS requirements found in BPC 4427.6.

    Reference: BPC 4017.3, 4056, 4427.2(i), 4427.6.

20. **QUESTION**: In the emergency room, when the pharmacy is not open, the physician will remove from the ADDS and dispense no more than a 72-hour supply of drugs to a patient to ensure a drug regimen is immediately commenced and continued pursuant to Business and Professions Code section 4068. Is the hospital pharmacy required to license the ADDS in the emergency room if the ADDS is primarily used for the administration of doses to patients in the emergency room, but occasionally used to dispense a 72-hour supply of drugs to a patient discharged from the emergency room for doses removed from the ADDS by the physician?

    ANSWER: Yes, the ADDS will be required to be licensed. The hospital pharmacy is only exempt from licensing the ADDS when the acute care hospital pharmacy solely uses the ADDS to administer drugs. When drugs from an ADDS is used to dispense drugs to a patient, the exemption no longer applies.

    While the ADDS must be licensed, as long as the physician removes the dangerous drug or device from the ADDS to dispense to the patient, the ADDS is not considered to be an APDS and need not follow the APDS requirements found in BPC 4427.6.

    Reference: BPC 4017.3, 4068, 4427.2(i), 4427.6

ADDS in Correctional Clinics:

21. QUESTION: Is the correctional clinics separately licensed from the ADDS license?

ANSWER: Yes. The correctional clinic is licensed pursuant to Business and Professions Code section 4187.1, which allows the correctional clinic to obtain drugs from a licensed correctional pharmacy, from the Department of Corrections and Rehabilitation's Central Fill Pharmacy, or from another correctional clinic licensed by the board within the same institution, for the administration or dispensing of drugs or devices.

Reference: BPC 4187, 4187.1, 4187.5, 4427.2, 4400(z)(aa)

ADDS in Clinics:

22. QUESTION: Our pharmacy is a located within a comprehensive health center. The clinics, under the same ownership as the pharmacy, are licensed with the Board and have ADDS located in secure medication rooms only accessible by licensed health care practitioners. If the clinic is licensed pursuant to Business and Professions Code section 4180, will the ADDS be required to be licensed?

ANSWER: The answer depends.

a. Pursuant to Business and Professions Code section 4427.3(a)(3), if the pharmacy owns, leases, or operates the ADDS, owns the drugs in the ADDS, , then the pharmacy is required to obtain licensure for each of the ADDS locations.
b. Pursuant to Business and Professions Code section 4186, if the clinic is licensed by the Board pursuant to Business and Professions Code section 4180, and the clinic develops and implements the written policies and procedures, the clinic reviews the drugs contained within the ADDS, and the clinic is responsible for the operations and maintenance of the ADDS, then the clinic is not required to obtain a license for the ADDS.

References: BPC 4186, 4427.3(a)(3)

ADDS in Medical Offices operated by a pharmacy:

23. QUESTION: We are a nonresident pharmacy licensed in California and would like to install and operate an ADDS in a physician's office. How can we apply for an ADDS license?

ANSWER: Nonresident pharmacies cannot apply for an ADDS license for an ADDS located in California. An ADDS license can only be issued to the holder of a current, valid, and active pharmacy license of a pharmacy located and licensed in California.

Reference: BPC 4427.2(b)

Miscellaneous:

24. QUESTION: Our pharmacy uses an ADDS to store controlled and noncontrolled substances. Are we required to obtain a Drug Enforcement Administration (DEA) registration for the ADDS to store controlled substances?

ANSWER: Although this question falls under the purview of DEA, the board's current understanding is that drugs stored in an ADDS and used as an emergency kit only in a skilled nursing facility may not be required to obtain a DEA registration. However, depending on the type of ADDS and if the intended use is more than serving as an emergency kit, the board suggests the pharmacy contact the DEA and inquire whether registration is required.

Reference: 21 CFR 1300.01(b), 1301.17(c), 1301.27, 1304.04

25. QUESTION: Who is authorized to restock the ADDS? (This does not apply to EMS ADDS)

ANSWER: The answer depends on the location of the ADDS.

- If the ADDS is located in a health facility licensed pursuant to HSC 1250 that complies with HSC 1261.6, the ADDS may be stocked by a pharmacist, a pharmacy technician or intern pharmacist under supervision of a pharmacist. If the ADDS utilizes removable pockets, cards, drawers, or similar technology, or unit of use, or single dose containers, and the facility in conjunction with the pharmacy has developed policies and procedures to ensure the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS, then the facility and contracted personnel authorized by law to administer drugs may also restock the ADDS.
- If the ADDS is located adjacent to the secured pharmacy area of the pharmacy holding the ADDS license, then a pharmacist, pharmacy intern or pharmacy technician under the supervision of a pharmacist may restock the ADDS.
- If the ADDS is located in a Correctional Clinic, then the stocking may be done by a pharmacist, an intern pharmacist or pharmacy technician, acting under the supervision of a pharmacist.
- If the ADDS is located in a clinic of a "covered entity," a clinic licensed pursuant to HSC 1204 or 1204.1 or BPC 4180 or 4190, then the stocking of the ADDS may be performed by a pharmacist, pharmacy technician or intern pharmacist under the supervision of a pharmacist.
- If the ADDS, used as an APDS, is located and operated in a medical office or other location where patients are regularly seen for purpose of diagnosis and treatment, and is only used to dispense dangerous drugs and dangerous devices to patients of the practice, by a pharmacy, then the stocking of the APDS may be performed by a pharmacist, pharmacy technician or intern pharmacist under the supervision of a pharmacist.

Reference: BPC 4127.3, 4186, 4187.5, 4119.11, 4427.4, HSC 126.1.6

Attachment 7

A hardcopy of these documents will be made available upon request.
Requests may be emailed to debbie.damoth@dca.ca.gov.