California State Board of Pharmacy
2720 Gateway Oaks Drive, Ste 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

To: Board Members

Subject: Agenda Item VII. Discussion and Consideration of Proposal to Amend Board's Fees Schedule Including Proposed Changes to Business and Professions Code Section 4400

Relevant Law

Business and Professions Code section 4400 generally establishes the Board's statutory minimum and maximum fees for applications and renewals. Subsection (p) further specifically states that it is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

Background

As indicated previously in this report, the Board's fund does not meet the requirements of the law. In recognition of this, the Board contracted for an independent fee analysis. The results of the fee audit demonstrate that the Board is not fully recovering its costs. Further, the Board is scheduled to run out of money to operate in FY 2026-27.

There are a number of reasons contributing to the increase in expenditures. Over the past five years the board has experienced:

- 60% increase in state distributed costs (pro rata).
- 23% increase in enforcement related costs.
- 26% increase in personnel.

Increases in enforcement related costs are attributed in large part to increases in the hourly rate assessed for AGO services, including a 30% increase in attorney services and 70% increase in paralegal services. Increases in personnel costs are attributed in part to salary increases established through collective bargaining, but also in response to new legislative mandates without commensurate increases in revenue.

History of Fees

The Board's last fee bill was SB 1039 (Chapter 799, Statutes 2016). The new fees became effective July 1, 2017. At that time not all fees were increased. As a precursor to the bill, in 2015 the DCA performed a fee audit for the Board. The Board's authorized budget at that time was $19,770,000. (Prior to that bill, the Board completed an audit of its fees in 2008 followed by a fee bill in 2009.)

In April 2020, in response to major budget adjustments impacting the Board,

including those identified above, fees were raised via regulation to existing statutory maximums.

Comparisons of Other Regulatory Fees

The California Department of Public Health Center for Health Care Quality Licensing and Certification publishes its health care facilities fees on an annual basis. The establishment of fees varies based on the type of facility. Further, some fees are assessed per facility while others are assessed per bed. Examples are provided below:

Correctional Treatment Centers - $1,782/bed
Primary Care Clinics - $2,231/facility
General Acute Care Hospital - $828/bed
Surgical Clinics - $7,724/facility

In addition, below are examples from several programs within the Department of Consumer Affairs:

Physicians and Surgeons
Application fee: $491 (includes $49 fingerprint fee)
Licensure fee: $808 (includes $25 scholarship) Fee may be reduced
Renewal Fee: $910 (biennial renewal that includes CURES fees)

Dentists
Total initial license fee $3,384.75 – 3,619.75 (Licensure by WREB Examination)
Total initial license fee $3,494 (Licensure by ADEX Examination)
Total initial licensure fee $1,199.75 (Licensure by portfolio)
Total initial licensure fee $1,559.75 (Licensure by Residency)
Total initial licensure fee $1,175 (Licensure by Credential)
Renewal fee $650 (biennial)

Registered Dental Assistance
Total initial licensure: $158
Total initial licensure with Practical and Written Exam $644.75
(Allows extended functions)
Renewal: $100 (biennial)

Private Post-Secondary Education
Approval non-accredited: $5,000
Approval accredited: $750
Approval addition of separate branch: $3,000
Change of Location: $500
Renewal non-accredited: $3,500
Renewal non-accredited branch: $3,000
Renewal accredited institution: $500

Summary of Changes Recommended

Increases in compounding related facilities, including sterile compounding facilities, satellite compounding facilities and centralized hospital pharmacies are larger than for most other fees. For each of these license types an inspection is required as a

precursor to licensure and renewal.

The largest fee increases are for outsourcing facilities. This is the most prominent area where the Board was not recovering the costs to perform the services. As indicated in the attachment, the fees being recommended are in line with fees assessed by the FDA. Specifically, the FDA assesses an annual establishment fee of $18,661 for non-small business entities. The FDA also assesses a separate reinspection fee of 17,823. These fees are adjusted annually for inflation. Further, staff note that the Board performs annual inspections of outsourcing facilities; however, the FDA does not.

The scope of the fee change varies based on the license type. As recommended the intern application fee, pharmacy technician application and renewal fees and pharmacist renewal fees will be reduced. Further, several license would not experience a fee increase based on legislation unless the Board raised fees via regulation after statutory changes become effective. As an example, the current advanced practice pharmacist application and renewal fees are $300. As proposed the statutory minimum would remain $300 and a new statutory maximum would be added. As another example, the veterinary food-animal drug retailer renewal fee would remain at $610 with a new maximum range established using the model offered by the fee auditor.

During the October Board Meeting, members voted to pursue a statutory change to the board's fee schedule and requested additional changes to the proposed fees for further consideration.

<u>For Member Discussion and Consideration</u>
During the meeting members will have the opportunity to review the revised proposal that incorporates feedback from the last discussion. As proposed based on projections, the revised fee schedule would result in approximately $35,500,666 annually in application and renewal fees. Additionally, Board staff are recommending a delayed effective date of January 1, 2025, which would allow for the necessary programming changes and application and renewal form changes.

Attachment 1 includes a summary chart detailing the new proposed fee ranges. Attachment 2 includes the proposed statutory language.

Attachment 1

License Type	Current Range	Current Fee	Recommendation	Comments
Pharmacy Application	$ 520 - 570	$ 570.00	$750 - 2,000	
Temp Pharmacy Application	$ 250 - 325	$ 325.00	$1,600 - 2,740	Note: Some applicants are abusing temp process and stalling on providing information for permanet licensure which is driving up the cost for pharmacy applications in general.
Pharmacy Renewal	$ 665 - 930	$ 930.00	$ 1,025 - 2,000	Note: Recommending that all pharmacy (HSP, DRM, LCFs) have the same renewal fee.
Pharmacist Exam Application	$ 260 - 285	$ 285.00	$ 260 - 285	
Pharmacist Exam Retake	$ 260 - 285	$ 285.00	$ 260 - 285	The Board does not charge for a retake of the NAPLEX.
Regrade	$ 90 - 115	$ 115.00	$ 115 - 200	
Pharmacist License	$ 195 - 215	$ 215.00	$ 195 - 215	
Pharmacist Renewal	$ 360 - 505	$ 505.00	$ 360 - 450	Biennial renewal. Renewal would be set at $450 and could be further lowered to $360.
WLS/3PL Application& Renewal	$ 780 - 820	$ 820.00	$ 1,000 - 1,411	
WLS/3PL Application 20+	$ 300 - 225	$ 300.00	$ 1,000 - 1,411	Recommend repeal
WLS/3PL Temp Fee	$ 715 - 550	$ 715.00	$ 715 - 1,009	
Hypodermic Application	$ 170 - 240	$ 240.00	$ 550 - 775	
Hypodermic Renewal	$ 200 - 280	$ 280.00	$ 400 - 561	
Designated Rep Application	$ 150 - 210	$ 210.00	$ 345 - 485	Note: Designated Rep 3PL audit recommendation is higher. Recommend keeping same as other DRs.
Designated Rep Renewal	$ 215 - 300	$ 300.00	$ 388 - 547	
Designated Rep Vet Application	$ 150 - 210	$ 210.00	$ 345 - 485	
Designated Rep Vet Renewal	$215 - 300	$ 300.00	$ 388 - 547	
Nonresident WLS/3PL	$ 780 - 820	$ 820.00	$ 1,000 - 1,411	
Nonresident WLS/3PL 20+	$ 300 - 225	$ 300.00	$ 810 - 1,143	
Nonresident WLS/3PL Temp	$ 715 - 550	$ 715.00	$ 715 - 1,009	
Nonresident WLS/3PL Renewal	$ 780 - 820	$ 820.00	$ 1,000 - 1,411	
Evaluate of CE Course cost/hour	$40	$ 40.00	$40	Note: Not included in audit as workload is variable
Intern Application	$ 165 - 230	$ 230.00	$ 175 - 245	
Transfer Intern Hours	$ 25 - 30	$ 30.00	$ 120 - 168	
Change of Name	$ 35 - 45	$ 45.00	$ 206 - 282	Changes related to entities.
Change of Permit	$ 100 - 130	$ 130.00	$ 395 - 557	Note: Change of permits are very labor intensive depending on the scope of the change.
Clinic Application	$ 520 - 570	$ 570.00	$ 620 - 873	Note: Recommendation from auditor for government owned is more. Recommend government owned pay same as other clinics
Clinic Renewal	$ 325 - 365	$ 365.00	$ 400 - 561	

Pharmacy Technician Application	$ 140 - 195	$ 195.00	$ 120 - 165	
Pharmacy Technician Renewal	$ 140 - 195	$ 195.00	$ 125 - 180	Biennial renewal. Fee would be set at $180 and could be further lowered to $125.
Veterinary FADR Application	$ 435 - 610	$ 610.00	$ 610 - 825	
Veterinary FADR Renewal	$ 330 - 460	$ 460.00	$ 460 - 561	
Veterinary FADR Temp	$ 250.00	$ 250.00	$ 520 - 732	
Retired Pharmacist	$ 35 - 45	$ 45.00	$ 50 - 100	
Sterile Compounding/Hospital Satellite Ap	$ 1,645 - 2,305	$ 2,305.00	$ 3,875 - 5,466	Note: Accredidiation by NABP is cost of application fee plus $4,500 for sterile compounding pharmacy. Additional costs are also assessed if an extended inspection is required.
Sterile Compounding/Hospital Satellite Re	$ 1,325 - 1,855	$ 1,855.00	$ 4,085 - 5,762	
Sterile Compounding/Hospital Satellite Te	$ 550 - 715	$ 715.00	$ 1,065 - 1,503	
Nonresident Sterile Compounding App	$ 2,380 - 3,335	$ 3,335.00	$ 8,500 - 16,502	
Nonresident Sterile Compounding Renewa	$ 2,270 - 3,180	$ 3,180.00	$ 8,500 - 17,040	
Nonresident Sterile Compounding Temp	$ 715.00	$ 715.00	$ 1,500 - 2,000	
Nonresident Sterile Travel Costs	Varies			
Outsourcing Application	$ 2,270 - 3,180	$ 3,180.00	$ 25,000 - 35,256	Note: FDA currently assess an annual establishment fee of $18,661 with an inspection fee of $17,823 when conducted. This inspection fee is in additional to the establishment fee. FDA established reduced establishment fee for small business. Fee for small business annual establishment fee is $5,491.
Outsourcing Renewal	$ 1,325 - 1,855	$ 1,885.00	$ 25,000 - 41,366	
Outsourcing Temp	$ 715.00	$ 715.00	$ 4,000 - 5,642	
Nonresident Outsourcing Application	$ 2,380 - $3,335	$ 3,335.00	$ 28,500 - 42,318	
Nonresident Outsourcing Renewal	$ 2,270 - $3,180	$ 3,180.00	$ 28,500 - 46,353	
Nonresident Outsourcing Temp	$ 715.00	$ 715.00	$ 4,000 - 5,642	
Nonresident Outsourcing Travel	varies			
Centralized Hospital Packaging Applicatior	$ 820 - 1,150	$ 1,150.00	$ 3,815 - 5,318	
Centralized Hospital Packaging Renewal	$ 805 - 1,125	$ 1,125.00	$ 2,912 - 4,107	
Correctional Clinic Application	$ 520 - 570	$ 570.00	$ 620 - 873	
Correctional Clinic Renewal	$ 325 - 360	$ 360.00	$ 400 - 561	
Correctional Clinic ADDS	$ 200.00	$ 200.00	$ 500 - 705	
Automated Drug Delivery System Applicat	$ 200 - 250	$ 200.00	$ 525 - 741	
Automated Drug Delivery System Renewa	$ 200 - 250	$ 200.00	$ 453 - 639	
Remote Dispensing Site Pharmacy Applica	$ 520 - 570	$ 570.00	$ 1,730 - 2,440	
Remote Dispensing Site Pharmacy Renewa	$ 655 - 930	$930	$1,025 - $2,000	

Remote Dispensing Site Pharmacy temp	$ 325.00	$ 325.00	$ 890 - 1,199	
Clinic Co-location Agreement	$ 750.00	$ 507.00		Note: Fee needs to be removed. Authority to co-locate was rescinded
Wholesaler ESMP	$ 780.00	$ 780.00	$ 810 - 1,143	
EMSADDS Application	$ 100.00	$ 100.00	$ 150 - 380	
EMSADDS Renewal	$ 100.00	$ 100.00	$ 200 - 273	
Designated Paramedic Application	$ 140.00	$ 140.00	$ 350 - 494	
Designated Paramedic Renewal	$ 140.00	$ 140.00	$ 200 - 292	
Nonresident Pharmacy App	$ 520 - 570	$ 570.00	$ 2,427 - 3,424	
Nonresident Pharmacy Temp	$ 250 - 325		$ 2,000 - 2,469	
Nonresident Pharmacy Renewal	$ 665 - 930	$ 930.00	$ 1,025 - 2,000	
Change of PIC/DRIC/RM	$100 - 130	$ 130.00	$ 250 - 353	
Advanced Practice Pharmacist Application	$ 300.00	$ 300.00	$ 300 - 418	
Advanced Practice Pharmacist Renewal	$ 300.00	$ 300.00	$ 300 - 418	Biennial renewal
Duplicate Cert	$ 35 - 45	$ 45.00	$ 75 - $100	
			$35,500,666	

Attachment 2

ARTICLE 23. Revenue and Renewal [4400 - 4409]
(Article 23 added by Stats. 1996, Ch. 890, Sec. 3.)

Proposed Amendment to 4400.
The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a pharmacy license shall be seven hundred fifty dollars ($750) and may be increased to two thousand dollars ($2,000) ~~five hundred twenty dollars ($520) and may be increased to five hundred seventy dollars ($570)~~. The fee for the issuance of a temporary pharmacy permit shall be one thousand six hundred dollars ($1,600) and may be increased to two thousand seven hundred forty dollars ($2,740) ~~two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325)~~.

(a)(1) The fee for a nonresident pharmacy license shall be two thousand four hundred twenty-seven dollars ($2,427) and may be increased to three thousand four hundred twenty-four dollars ($3,424). The fee for the issuance of a temporary nonresident pharmacy permit shall be two thousand dollars ($2,000) and may be increased to two thousand four hundred sixty-nine dollars ($2,469).(b) The fee for a pharmacy license annual renewal shall be ~~six hundred sixty-five dollars ($665) and may be increased to nine hundred thirty dollars ($930)~~ one thousand twenty-five dollars ($1,025) and may be increased to two thousand dollars ($2,000).

(b)(1) The fee for a nonresident pharmacy license annual renewal shall one thousand twenty-five dollars ($1,025) and may be increased to two thousand dollars ($2,000).

(c) The fee for the pharmacist application and examination shall be two hundred sixty dollars ($260) and may be increased to two hundred eighty-five dollars ($285)

(d) The fee for regrading an examination shall be ~~ninety dollars ($90) and may be increased to~~ one hundred fifteen dollars ($115) and may be increased to two hundred dollars ($200). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license shall be one hundred ninety-five dollars ($195) and may be increased to two hundred fifteen dollars ($215). The fee for a pharmacist biennial renewal shall be four fifty hundred dollars ($450) and may be reduced to three hundred sixty dollars ($360). ~~and may be increased to five hundred five dollars ($505).~~

(f) The fee for a wholesaler or third-party logistics provider license and annual renewal shall be one thousand dollars ($1,000) and may be increased to one thousand four hundred eleven dollars ($1,411) ~~seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820)~~. ~~The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225).~~ A temporary license fee shall be seven hundred fifteen dollars ($715) and may be increased to one thousand nine dollars ($1,009) ~~decreased to no less than five hundred fifty dollars ($550)~~.

(g) The fee for a hypodermic license shall be five hundred fifty dollars ($550) and may be increased to seven hundred seventy-five ($775) ~~one hundred seventy dollars ($170) and may be increased to two hundred forty dollars ($240)~~. The fee for a hypodermic license renewal shall be four hundred dollars ($400) and may be increased to five hundred sixty-one dollars ($561) ~~two hundred dollars ($200) and may be increased to two hundred eighty dollars ($280)~~.

(h)(1) The fee for application, investigation, and issuance of a license as a designated representative pursuant to Section 4053, as a designated representative-3PL pursuant to Section 4053.1, or as a designated representative-reverse distributor pursuant to Section 4053.2 shall be three hundred forty-five dollars ($345) and may be increased to four hundred eighty-five dollars ($485). ~~one hundred fifty dollars ($150) and may be increased to two hundred ten dollars ($210).~~

(2) The fee for the annual renewal of a license as a designated representative, designated representative-3PL, or designated representative-reverse distributor shall be three hundred eighty-eight dollars ($388) and may be increased to five hundred forty-seven dollars ($574) ~~two hundred fifteen dollars ($215) and may be increased to three hundred dollars ($300)~~.

(i)(1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be three hundred forty-five dollars ($345) and may be increased to four hundred eighty-five dollars ($485) ~~one hundred fifty dollars ($150) and may be increased to two hundred ten dollars ($210)~~.

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be three hundred eighty-eight dollars ($388) and may be increased to five hundred and forty-seven dollars ($547) ~~two hundred fifteen dollars ($215) and may be increased to three hundred dollars ($300)~~.

(j)(1) The application fee for a nonresident wholesaler or third-party logistics provider license issued pursuant to Section 4161 shall be one thousand dollars ($1,000) and may be increased to one thousand four hundred eleven dollars ($1,411) ~~seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820)~~.

~~(2) For nonresident wholesalers or third-party logistics providers that have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225).~~ A temporary license fee shall be seven hundred fifteen dollars ($715) and may be increased to one thousand nine dollars ($1,009). ~~decreased to no less than five hundred fifty dollars ($550).~~

(3) The annual renewal fee for a nonresident wholesaler license or third-party logistics provider license issued pursuant to Section 4161 shall be ~~seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820)~~ one thousand dollars ($1,000) and may be increased to one thousand four hundred eleven dollars ($1,411).

(k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars ($40) per course hour.

(l) The fee for an intern pharmacist license shall be one hundred seventy-five dollars ($175) and may be increased to two hundred and forty-five dollars ($245) ~~one hundred sixty-five dollars ($165) and may be increased to two hundred thirty dollars ($230)~~. The fee for transfer of intern hours or verification of licensure to another state shall be one hundred twenty dollars ($120) and may be increased to one hundred sixty-eight dollars ($168) ~~twenty-five dollars ($25) and may be increased to thirty dollars ($30)~~.

(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be seventy-five dollars ($75) and may be increased to one hundred dollars ($100) ~~thirty-five dollars ($35) and may be increased to forty-five dollars ($45)~~.

(o) The fee for processing an application to change information on a premises license record shall be three hundred ninety-five dollars ($395) and may be increased to five hundred fifty-seven dollars ($557). ~~one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).~~

———(o)(1) The fee for processing an application to change a name or correct an address on a premises license record shall be two hundred six dollars ($206) and may be increased to two hundred eighty-two dollars ($282).

———(o)(2) The fee for processing an application to change a pharmacist-in-charge, designated representative-in-charge, or responsible manager on a premises license record shall be two hundred fifty dollars ($250) and may be increased to three hundred fifty-three dollars ($353).

(p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(q) The fee for any applicant for a clinic license shall be six hundred twenty dollars ($620) and may be increased to eight-hundred seventy-three dollars ($873). ~~five hundred twenty dollars ($520) for each license and may be increased to five hundred seventy dollars ($570).~~ The annual fee for renewal of the license shall be four hundred dollars ($400) and may be increased to five hundred sixty-one dollars ($561) ~~three hundred twenty-five dollars ($325) for each license and may be increased to three hundred sixty dollars ($360)~~.

(r) The fee for the issuance of a pharmacy technician license shall be one hundred twenty dollars ($120) and may be increased to one hundred sixty-five dollars

($165). ~~one hundred forty dollars ($140) and may be increased to one hundred ninety-five dollars ($195).~~ The fee for renewal of a pharmacy technician license shall be one hundred ~~fifty~~ eighty dollars ($180) and may be reduced to one hundred twenty-five dollars ($125). ~~be increased to one hundred ninety-five dollars ($195).~~

(s) The fee for a veterinary food-animal drug retailer license shall be ~~four hundred thirty-five dollars ($435) and may be increased to~~ six hundred ten dollars ($610) and may be increased to eight hundred twenty-five dollars ($825). The annual renewal fee for a veterinary food-animal drug retailer license shall be ~~three hundred thirty dollars ($330) and may be increased to~~ four hundred sixty dollars ($460) and may be increased to five hundred sixty-one dollars ($561). The fee for the temporary license shall be five hundred twenty dollars ($520) and may be increased to seven hundred thirty-two dollars ($732).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be ~~thirty-five dollars ($35) and may be increased to forty-five dollars ($45)~~ fifty dollars ($50) and may be in increased to one hundred dollars ($100).

(u) The fee for issuance of a sterile compounding pharmacy license or a hospital satellite compounding pharmacy shall be three thousand eight hundred seventy - five dollars ($3,875) and may be increased to five thousand four hundred sixty-six dollars ($5,466). ~~one thousand six hundred forty-five dollars ($1,645) and may be increased to two thousand three hundred five dollars ($2,305).~~ The fee for a temporary license shall be one thousand sixty-five dollars ($1,065) and may be increased to one thousand five hundred three dollars ($1,503). ~~five hundred fifty dollars ($550) and may be increased to seven hundred fifteen dollars ($715).~~ The annual renewal fee of the license shall be four thousand eight-five dollars ($4,085) and may be increased to five thousand seven hundred sixty-two dollars ($5,762) ~~one thousand three hundred twenty-five dollars ($1,325) and may be increased to one thousand eight hundred fifty-five dollars ($1,855)~~.

(v) The fee for the issuance of a nonresident sterile compounding pharmacy license shall be eight thousand five hundred dollars ($8,500) and may be increased to sixteen thousand five hundred two dollars ($16,502). ~~two thousand three hundred eighty dollars ($2,380) and may be increased to three thousand three hundred thirty-five dollars ($3,335).~~ The annual renewal of the license shall be ~~two thousand two hundred seventy dollars ($2,270) and may be increased to three thousand one hundred eighty dollars ($3,180)~~ eight thousand five hundred dollars ($8,500) and may be increased to seventeen thousand forty dollars ($17,040). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant. The fee for a temporary license shall be

one thousand five hundred dollars ($1,500) and may be increased to two thousand dollars ($2,000).

(w) The fee for the issuance of an outsourcing facility license shall be twenty-five thousand dollars ($25,000) and may be increased to thirty-five thousand two hundred fifty-six dollars ($35,256) ~~two thousand two hundred seventy dollars ($2,270) and may be increased to up to three thousand one hundred eighty dollars ($3,180) by the board~~. The fee for the renewal of an outsourcing facility license shall be twenty-five thousand dollars ($25,000) and may be increased to forty-one thousand three hundred sixty-six dollars ($41,366) ~~one thousand three hundred twenty-five dollars ($1,325) and may be increased to up to one thousand eight hundred fifty-five dollars ($1,855) by the board~~. The fee for a temporary outsourcing facility license shall be ~~seven hundred fifteen dollars ($715)~~ four thousand dollars ($4,000) and may be increased to five thousand six hundred forty-two dollars ($5,642).

(x) The fee for the issuance of a nonresident outsourcing facility license shall be twenty-eight thousand five hundred dollars ($28,500) and may be increased to forty-two thousand three hundred eighteen dollars ($42,318). ~~two thousand three hundred eighty dollars ($2,380) and may be increased to up to three thousand three hundred thirty-five dollars ($3,335) by the board.~~ The fee for the renewal of a nonresident outsourcing facility license shall be twenty-eight thousand five hundred dollars ($28,500) and may be increased to forty-six thousand three hundred fifty-three dollars ($46,353) ~~two thousand two hundred seventy dollars ($2,270) and may be increased to up to three thousand one hundred eighty dollars ($3,180) by the board~~. In addition to paying that application fee, the nonresident outsourcing facility shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4129.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant. The fee for a temporary nonresident outsourcing license shall be four thousand dollars ($4,000) and may be increased to five thousand six hundred forty-two dollars ($5,642).

(y) The fee for the issuance of a centralized hospital packaging license shall be three thousand eight hundred fifteen dollars ($3,815) and may be increased to five thousand three hundred eighteen dollars ($5,318) ~~eight hundred twenty dollars ($820) and may be increased to one thousand one hundred fifty dollars ($1,150)~~. The annual renewal of the license shall be two thousand nine hundred twelve dollars ($2,912) and may be increased to four thousand one hundred seven dollars ($4,107) ~~eight hundred five dollars ($805) and may be increased to one thousand one hundred twenty-five dollars ($1,125)~~.

(z) The fee for the issuance of a license to a correctional clinic pursuant to Article 13.5 (commencing with Section 4187) ~~that is not owned by the state~~ shall be six hundred twenty dollars ($620) and may be increased to eight hundred seventy-

three dollars ($873). ~~five hundred twenty dollars ($520) and may be increased to five hundred seventy dollars ($570).~~ The annual renewal fee for that correctional clinic license shall be four hundred dollars ($400) and may be increased to five hundred sixty-one dollars ($561) ~~three hundred twenty-five dollars ($325) and may be increased to three hundred sixty dollars ($360)~~.

(z)(1) The fee for the issuance of an ADDS license to a correctional clinic pursuant to Article 13.5 (commencing with Section 4187) shall be five hundred dollars ($500) and may be increased to seven hundred five dollars ($705). The annual renewal fee for the correctional clinic ADDS shall be four hundred dollars ($400) and may be increased to five hundred sixty-one dollars ($561).

(aa) ~~Beginning on and after July 1, 2019, t~~The fee for an ADDS license shall be five hundred twenty-five dollars ($525) and may be increased to seven hundred forty-one dollars ($741) ~~two hundred dollars ($200) and may be increased to two hundred fifty dollars ($250)~~. The fee for the annual renewal of the license shall be four hundred fifty-three dollars ($453) and may be increased to six hundred thirty-nine dollars ($639) ~~two hundred dollars ($200) and may be increased to two hundred fifty dollars ($250)~~.

(ab) The application and initial license fee for a remote dispensing site pharmacy application shall be one thousand seven hundred thirty dollars ($1,730) and may be increased to two thousand four hundred forty dollars ($2,440). The fee for the annual renewal shall be one thousand twenty-five dollars ($1,025) and may be increased to two thousand dollars ($2,000). The fee for a temporary license shall be eight hundred ninety dollars ($890) and may be increased to one thousand one hundred ninety-nine dollars ($1,199).

(ab) The application and initial license fee to operate EMSADDS shall be one hundred fifty dollars ($150) and may be increased to three hundred eighty dollars ($380) per machine. The fee for the annual renewal shall be two hundred dollars ($200) and may be increased to two hundred seventy-three dollars ($273). The license fee may not be transferred to a different location if the EMSADDS is moved. The application and renewal fee for a licensed wholesaler that is also an emergency medical services provider agency shall be eight hundred ten dollars ($810) and may be increased to one thousand one hundred forty-three dollars ($1,143).

(ac) The fee for application and issuance of an initial license as a designated paramedic shall be three hundred fifty dollars ($350) and may be increased to four hundred ninety-four dollars ($494). The fee of biennial renewal shall be two hundred dollars ($200) and may be increased to two hundred ninety-two dollars ($292).

(ad) The fee for an application for an advanced practice pharmacist license and renewal of advanced practice pharmacist license shall be three hundred dollars ($300) and may be increased to four hundred eighteen dollars ($418).

(ae) This section shall become operative on ~~July 1, 2021~~ January 1, 2025.

Proposed Amendment to 4119.01.

(a) Notwithstanding any other law, a pharmacy, or a licensed wholesaler that is also an emergency medical services provider agency, may restock dangerous drugs or dangerous devices into an emergency medical services automated drug delivery system (EMSADDS) that is licensed by the board under this section. Dangerous drugs and dangerous devices stored or maintained in an EMSADDS shall be used for the sole purpose of restocking a secured emergency pharmaceutical supplies container as authorized in subdivision (b) of Section 4119. The EMSADDS may be used only if all of the following conditions are met:

(1) The emergency medical services provider agency obtains a license from the board to operate the EMSADDS. As a requirement for licensure, the EMSADDS shall be located on the premises of a fire department headquarters, a fire station, or at an emergency medical services provider agency's location. A separate license shall be required for each location.

(A) As part of its license application, the emergency medical services provider agency shall provide: the address where the EMSADDS will be located; the name of the medical director responsible for overseeing the emergency medical services provider agency; the name of any designated pharmacist or licensed designated paramedic who is responsible for performing the duties as required under this section; the policies and procedures detailing the provisions under which the EMSADDS will operate; and the name and license number of the pharmacy or emergency medical services provider agency wholesaler that will furnish the dangerous drugs and dangerous devices through the EMSADDS.

~~(B) The application and initial license fee to operate EMSADDS shall be one hundred dollars ($100) per machine. The license shall be renewed annually. The license fee may not be transferred to a different location if the EMSADDS is moved. The penalty fee for failure to renew an EMSADDS license shall be thirty-five dollars ($35).~~

~~(C) The application and renewal fee for a licensed wholesaler that is also an emergency medical services provider agency shall be seven hundred eighty dollars ($780).~~

(2) Each EMSADDS shall collect, control, and maintain all transaction information necessary to accurately track the movement of drugs into and out of the system for purposes of security, accuracy, and accountability.

(3) The medical director and designated pharmacist, or the medical director and the licensed designated paramedic, shall develop, adopt, and maintain policies and procedures detailing the provisions under which the EMSADDS will operate. At a minimum, the policies and procedures shall address (A) inventory controls, (B) training, (C) storage and security of the dangerous drugs and dangerous devices, and (D) safeguards to limit access to the EMSADDS to authorized staff only.

(4) The licensed EMSADDS operator shall limit access to the EMSADDS only to employees of the operator who are licensed by the state and as authorized in this section.

(A) An EMSADDS may only be restocked by the medical director, a pharmacist, or a licensed designated paramedic, each of whom may possess and transport dangerous drugs or dangerous devices for that purpose. The transport of dangerous drugs or dangerous devices for restocking into an EMSADDS shall be done in a secured manner to prevent theft or unauthorized access, and shall be done under conditions appropriate to meet storage and handling requirements of the dangerous drugs or dangerous devices. While the dangerous drugs or dangerous devices may be transported, representatives shall not store a dangerous drug or dangerous device at an unlicensed location.

(B) Only a medical director, a pharmacist, or a paramedic may remove dangerous drugs or dangerous devices from an EMSADDS to fill a secured emergency pharmaceutical supplies container. This access shall be observed by a second person who is also a paramedic, a pharmacist, or a medical director. Both the individual who removes dangerous drugs or dangerous devices from the EMSADDS and the observer shall record their participation in the removal of the dangerous drugs or dangerous devices via their signatures or use of biometric identifiers. The restocking of the secured emergency pharmaceutical supplies container from the EMSADDS shall occur at the licensed location of the EMSADDS.

(C) A medical director, a pharmacist, or a licensed designated paramedic may remove outdated dangerous drugs or dangerous devices from an EMSADDS. Any outdated dangerous drugs or dangerous devices shall be provided to a licensed reverse distributor for destruction.

(5) Every EMSADDS operator shall perform monthly inventory and inventory reconciliation functions. The medical director, designated pharmacist, or licensed designated paramedic shall perform a reconciliation and prepare a written report based on written policies and procedures developed to maintain the security and quality of the dangerous drugs and dangerous devices. The written inventory reconciliation report shall include all of the following:

(A) A physical count of all quantities of dangerous drugs and dangerous devices stored in the EMSADDS.

(B) A review of all dangerous drugs and dangerous devices added into and removed from each EMSADDS since the last monthly inventory.

(C) A comparison of subparagraphs (A) and (B), and identification of any variances.

(D) A review of all individuals who accessed the EMSADDS since the last inventory and identification of unauthorized individuals accessing the EMSADDS or suspicious activity.

(E) Identification of possible causes of shortages and overages.

(6) The medical director and designated pharmacist, or medical director and licensed designated paramedic, shall be jointly responsible for monthly review of the inventory reconciliation report, the training, storage, and security of dangerous drugs and dangerous devices, and the restocking of the EMSADDS.

Any inventory losses from an EMSADDS shall be reported to the board within seven days from identification of the loss.

(7) In order for an individual to perform the functions of a licensed designated paramedic described in this section, that individual shall be licensed by the board pursuant to Section 4202.5. A paramedic who only restocks a secured emergency pharmaceutical supplies container from an EMSADDS need not be licensed with the board.

(8) A record of each access to the EMSADDS, as well as all records used to compile an inventory reconciliation report, shall be maintained at the operator's location for at least three years in a readily retrievable form. The records shall include the identity of every individual who accessed the system or witnessed such access; the date of each access; and the drug, dosage, form, strength, and quantity of dangerous drugs or dangerous devices added or removed.

(b) A violation of any of the provisions of this section shall constitute unprofessional conduct and provides the board the authority to take action against the EMSADDS operator's license.

Proposed Amendment to 4119.11.

(a) A pharmacy located in the state may provide pharmacy services to the patients of a "covered entity," as defined in Section 256b of Title 42 of the United States Code, through the use of an automated patient dispensing system located on the premises of the covered entity or on the premises of medical professional practices under contract to provide medical services to covered entity patients, which need not be the same location as the pharmacy, if all of the following conditions are met:

(1) The pharmacy obtains a license from the board to operate the automated patient dispensing system at the covered entity or affiliated site. As part of the application, the pharmacy shall provide the address at which the automated patient dispensing system shall be placed and identify the covered entity. A separate license shall be required for each location and shall be renewed annually concurrent with the pharmacy license. ~~The application and renewal fee shall be three hundred dollars ($300) and may be increased to five hundred dollars ($500). The board is authorized to lower the renewal fee to not less than two hundred dollars ($200) if a lower fee level will provide sufficient resources to support the regulatory activities~~.

(2) The pharmacy providing the pharmacy services to the patients of the covered entity, including, unless otherwise prohibited by any other law, patients enrolled in the Medi-Cal program, shall be under contract with that covered entity as described in Section 4126 to provide those pharmacy services through the use of the automated patient dispensing system.

(3) Drugs stored in an automated patient dispensing system shall be part of the inventory of the pharmacy providing pharmacy services to the patients of the covered entity and drugs dispensed from the automated patient dispensing system shall be considered to have been dispensed by that pharmacy.

(4) The pharmacy shall maintain records of the acquisition and disposition of dangerous drugs stored in the automated patient dispensing system separate from other pharmacy records.

(5) The pharmacy shall be solely responsible for the security, operation, and maintenance of the automated patient dispensing system.

(6) The pharmacy shall provide training regarding the operation and use of the automated patient dispensing system to both pharmacy and covered entity personnel using the system.

(7) The operation of the automated patient dispensing system shall be under the supervision of a licensed pharmacist acting on behalf of the pharmacy providing services to the patients of the covered entity. The pharmacist need not be physically present at the site of the automated patient dispensing system and may supervise the system electronically.

(8) Notwithstanding Section 4107, the board may issue a license for the operation of an automated patient dispensing system at an address for which it has issued another site license.

(9) The board, within 30 days after receipt of an application for an automated patient dispensing system license, shall conduct a prelicensure inspection at the proposed location of the automated patient dispensing system. Relocation of the automated patient dispensing system shall require a new application for licensure. Replacement of an automated patient dispensing system shall require notice to the board within 30 days.

(10) The automated patient dispensing system license shall be canceled by operation of law if the underlying pharmacy license is not current, valid, and active. Upon reissuance or reinstatement of the underlying pharmacy license, a new application for an automated patient dispensing system license may be submitted to the board.

(11) A pharmacy that holds an automated patient dispensing system license shall advise the board in writing within 30 days if use of the automated patient dispensing system is discontinued.

(b) For purposes of this section, the following definitions shall apply:

(1) An "automated drug delivery system" (ADDS) means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An ADDS shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

(2) An "automated patient dispensing system" (APDS) is an ADDS for storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.

(3) An "automated unit dose system" (AUDS) is an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions.

(c) (1) An automated patient dispensing system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

(2) Transaction information shall be made readily available in a downloadable format for review and inspection by individuals authorized by law. These records shall be maintained by the pharmacy for a minimum of three years.

(d) Drugs from the automated patient dispensing system may be dispensed directly to the patient, if all of the following requirements are met:

(1) The pharmacy shall develop, implement, and annually review written policies and procedures with respect to all of the following:

(A) Maintaining the security of the automated patient dispensing system and the dangerous drugs and devices within that automated patient dispensing system.

(B) Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the automated patient dispensing system and for which patients.

(C) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including those delivered via the automated patient dispensing system.

(D) Describing assignment of responsibilities to, and training of, pharmacy personnel, and other personnel using the automated patient dispensing system at the location where the automated patient dispensing system is placed, regarding maintenance and filing procedures for the automated patient dispensing system.

(E) Orienting participating patients on the use of the automated patient dispensing system, notifying patients when expected prescription medications are not available in the automated patient dispensing system, and ensuring that patient use of the automated patient dispensing system does not interfere with delivery of drugs and devices.

(F) Ensuring delivery of drugs and devices to patients expecting to receive them from the automated patient dispensing system if the automated patient dispensing system is disabled or malfunctions.

(2) The automated patient dispensing system shall only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drugs and devices from an automated patient dispensing system and whose use of the automated patient dispensing system meet the criteria pursuant to paragraph (1).

(3) The automated patient dispensing system shall have a means to identify each patient and only release the identified patient’s drugs and devices to the patient or the patient’s agent.

(4) A pharmacist shall perform all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation.

(5) Drugs shall be dispensed from the automated patient dispensing system only upon authorization from a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions.

(6) All prescribed drugs and devices dispensed from the automated patient dispensing system for the first time shall be accompanied by a consultation conducted by a pharmacist licensed by the board via a telecommunications link that has two-way audio and video.

(7) The automated patient dispensing system shall include a notice, prominently posted on the automated patient dispensing system, that provides the name, address, and telephone number of the pharmacy that holds the automated patient dispensing system license for that automated patient dispensing system.

(8) The labels on all drugs dispensed by the automated patient dispensing system shall comply with Section 4076 of this code and with Section 1707.5 of Title 16 of the California Code of Regulations.

(9) Any complaint, error, or omission involving the automated patient dispensing system shall be reviewed as part of the pharmacy's quality assurance program pursuant to Section 4125.

(10) The board shall not issue a pharmacy more than 15 licenses for automated patient dispensing system units under this section. Consistent with Section 4001.1, the board may adopt regulations to reduce the number of automated patient dispensing system licenses that may be issued to a pharmacy.

(11) The pharmacy holding the license for the automated patient dispensing system shall maintain the policies and procedures developed pursuant to paragraph (1) for three years after the last date of use of that automated patient dispensing system.

(e) Access to the automated patient dispensing system shall be controlled and tracked using an identification or password system or biosensor. A system that is accessed via a password system shall include a camera that records a picture of the individual accessing the machine. Picture records shall be maintained for a minimum of 180 days.

(f) The automated patient dispensing system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.

(g) The stocking of an automated patient dispensing system shall be performed by a pharmacist. If the automated patient dispensing system utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers as defined by the United States Pharmacopeia, the stocking system may be done outside of the facility and be delivered to the facility, if all of the following conditions are met:

(1) The task of placing drugs into the removable pockets, cards, drawers, similar technology, or unit of use or single dose containers is performed by a pharmacist,

or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

(2) The removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container.

(3) The pharmacy, in conjunction with the covered entity, has developed policies and procedures to ensure that the removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are properly placed into the automated patient dispensing system.

(h) Review of the drugs contained within, and the operation and maintenance of, the automated patient dispensing system shall be done in accordance with law and shall be the responsibility of the pharmacy. A pharmacist shall conduct the review on a monthly basis, which shall include a physical inspection of the drugs in the automated patient dispensing system, an inspection of the automated patient dispensing system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

(i) A pharmacy holding an automated patient dispensing system license shall complete a self-assessment, performed pursuant to Section 1715 of Title 16 of the California Code of Regulations, evaluating the pharmacy's compliance with pharmacy law relating to the use of the automated patient dispensing system. All information regarding operation, maintenance, compliance, error, omissions, or complaints pertaining to the automated patient dispensing system shall be included in the self-assessment.

(j) The pharmacy shall comply with all recordkeeping and quality assurance requirements pursuant to this chapter, and shall maintain those records within the pharmacy holding the automated patient dispensing system license and separately from other pharmacy records.

Proposed Amendment to BPC 4128.2.

(a) In addition to the pharmacy license requirement described in Section 4110, a centralized hospital packaging pharmacy shall obtain a specialty license from the board prior to engaging in the functions described in Section 4128.

(b) An applicant seeking a specialty license pursuant to this article shall apply to the board on forms established by the board.

(c) Before issuing the specialty license, the board shall inspect the pharmacy and ensure that the pharmacy is in compliance with this article and regulations established by the board.

(d) A license to perform the functions described in Section 4128 may only be issued to a pharmacy that is licensed by the board as a hospital pharmacy.

(e) A license issued pursuant to this article shall be renewed annually and is not transferrable.

(f) An applicant seeking renewal of a specialty license shall apply to the board on forms established by the board.

(g) A license to perform the functions described in Section 4128 shall not be renewed until the pharmacy has been inspected by the board and found to be in compliance with this article and regulations established by the board.

~~(h) Until July 1, 2017, the fee for issuance or annual renewal of a centralized hospital packaging pharmacy license shall be six hundred dollars ($600) and may be increased by the board to eight hundred dollars ($800).~~

Proposed Amendment to BPC 4161.

(a) A person located outside this state that (1) ships, sells, mails, warehouses, distributes, or delivers dangerous drugs or dangerous devices into this state or (2) sells, brokers, warehouses, or distributes dangerous drugs or devices within this state shall be considered a nonresident wholesaler or a nonresident third-party logistics provider.

(b) A nonresident wholesaler or nonresident third-party logistics provider shall be licensed by the board prior to shipping, selling, mailing, warehousing, distributing, or delivering dangerous drugs or dangerous devices to a site located in this state or selling, brokering, warehousing, or distributing dangerous drugs or devices within this state.

(c) (1) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler or nonresident third-party logistics provider from or through which dangerous drugs or dangerous devices are shipped, sold, mailed, warehoused, distributed, or delivered to a site located in this state or sold, brokered, warehoused, or distributed within this state. Each place of business may only be issued a single license by the board, except as provided in paragraph (2). A license shall be renewed annually and shall not be transferable.

(2) A nonresident wholesaler and a nonresident third-party logistics provider under common ownership may be licensed at the same place of business provided that all of the following requirements are satisfied:

(A) The wholesaler and the third-party logistics provider each separately maintain the records required under Section 4081.

(B) Dangerous drugs and dangerous devices owned by the wholesaler are not commingled with the dangerous drugs and dangerous devices handled by the third-party logistics provider.

(C) Any individual acting as a designated representative for the wholesaler is not concurrently acting as a designated representative-3PL on behalf of the third-party logistics provider. Nothing in this subparagraph shall be construed to prohibit an individual from concurrently holding a license to act as a designated representative and to act as a designated representative-3PL.

(D) The wholesaler has its own designated representative-in-charge responsible for the operations of the wholesaler and the third-party logistics provider has its own responsible manager responsible for the operations of the third-party logistics provider. The same individual shall not concurrently serve as the responsible manager and the designated representative-in-charge for a

wholesaler and a third-party logistics provider licensed at the same place of business.

(E) The third-party logistics provider does not handle the prescription drugs or prescription devices owned by a prescriber.

(F) The third-party logistics provider is not a reverse third-party logistics provider.

(G) The wholesaler is not acting as a reverse distributor.

(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler or a nonresident third-party logistics provider, on renewal of a nonresident wholesaler or nonresident third-party logistics provider license, or within 30 days of a change in that information:

(1) Its agent for service of process in this state.

(2) Its principal corporate officers, as specified by the board, if any.

(3) Its general partners, as specified by the board, if any.

(4) Its owners if the applicant is not a corporation or partnership.

(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.

(f) A nonresident wholesaler or nonresident third-party logistics provider shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.

(g) A nonresident wholesaler or nonresident third-party logistics provider shall maintain records of dangerous drugs and dangerous devices sold, traded, transferred, warehoused, or distributed to persons in this state or within this state, so that the records are in a readily retrievable form.

(h) A nonresident wholesaler or nonresident third-party logistics provider shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler or nonresident third-party logistics provider in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler or nonresident third-party logistics provider license in this state shall include a license verification from the licensing authority in the applicant’s state of residence. The board may waive the home state licensure requirement for a nonresident third-party logistics provider if the board inspects the location and finds it to be in compliance with this article and any regulations adopted by the board or the applicant provides evidence of its accreditation by the Drug Distributor Accreditation program of the National Association of Boards of Pharmacy. The nonresident third-party logistics provider shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the location, pursuant to subdivision (v) of Section 4400.

(i) (1) The board shall not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies

the board in writing of the identity and license number of the designated representative-in-charge.

(2) The board shall not issue or renew a nonresident third-party logistics provider license until the nonresident third-party logistics provider identifies a responsible manager and notifies the board in writing of the identity and license number of the designated representative-3PL who will be the responsible manager.

(j) The designated representative-in-charge shall be responsible for the compliance of the nonresident wholesaler with state and federal laws governing wholesalers. The responsible manager shall be responsible for the compliance of the nonresident third-party logistics provider's place of business with state and federal laws governing third-party logistics providers. A nonresident wholesaler or nonresident third-party logistics provider shall identify and notify the board of a new designated representative-in-charge or responsible manager within 30 days of the date that the prior designated representative-in-charge or responsible manager ceases to be the designated representative-in-charge or responsible manager.

(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. ~~A temporary license fee shall be five hundred fifty dollars ($550) or another amount established by the board not to exceed the annual fee for renewal of a license to compound sterile drug products.~~ When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a temporary license, nor for purposes of any disciplinary or license denial proceeding before the board, shall the temporary licenseholder be deemed to have a vested property right or interest in the license.

(l) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

Proposed Amendment to BPC 4202.5.

(a) The board may issue a designated paramedic license to an individual if he or she holds a license as a paramedic in this state and meets the criteria of this section.

(b) The board shall conduct a criminal background check of the applicant to determine if the applicant has committed acts that would constitute grounds for denial of licensure, pursuant to this chapter or Chapter 2 (commencing with Section 480) of Division 1.5.

(c) The board may suspend or revoke a license issued pursuant to this section on any ground specified in Section 4301.

(d) A license issued under this section is dependent on the validity of the holder's paramedic license and shall be automatically suspended if the individual's

paramedic license is expired, revoked, or otherwise invalidated by the issuing authority.

~~(e) The fee for application and issuance of an initial license as a designated paramedic shall be one hundred forty dollars ($140) for a two-year license. The biennial renewal shall be one hundred forty dollars ($140). The penalty fee for failure to renew an authorized paramedic license shall be sixty-five dollars ($65).~~

Proposed Amendment to BPC 4210. Advanced Practice Pharmacist License

(a) A person who seeks recognition as an advanced practice pharmacist shall meet all of the following requirements:

(1) Hold an active license to practice pharmacy issued pursuant to this chapter that is in good standing.

(2) (A) Satisfy any two of the following criteria:

(i) Earn certification in a relevant area of practice, including, but not limited to, ambulatory care, critical care, geriatric pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacotherapy, or psychiatric pharmacy, from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board.

(ii) Complete a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes the provision of direct patient care services with interdisciplinary teams.

(iii) Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.

(B) For purposes of this paragraph, if, as a condition of completion of one of the required criteria fulfillment of a second criterion is also required, that completion shall be deemed to satisfy this paragraph.

(3) File an application with the board for recognition as an advanced practice pharmacist.

(4) Pay the applicable fee to the board.

(b) An advanced practice pharmacist recognition issued pursuant to this section shall be valid for two years, coterminous with the certificate holder’s license to practice pharmacy.

~~(c) The board shall adopt regulations establishing the means of documenting completion of the requirements in this section.~~

~~(d) The board shall, by regulation, set the fee for the issuance and renewal of advanced practice pharmacist recognition at the reasonable cost of regulating advanced practice pharmacists pursuant to this chapter. The fee shall not exceed three hundred dollars ($300).~~