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

To: Members

From: Seung Oh, President
California State Board of Pharmacy

Re: Agenda Item VII. Discussion and Possible Action Regarding Executive Officer Exempt Level Change and Salary Increase

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Last year, I began communications with the Department of Consumer Affairs (DCA) to discuss the process for a Board to request a change in the exempt level and salary of its executive officer. Unlike other positions within the Board that are considered civil service positions, the executive officer position is an exempt position, with the salary determined by the Board and approved by the California Department of Human Resources (CalHR). The Board is required to discuss any such request and take formal action as a Board to initiate such a request.

In consultation with Olivia Trejo, Chief of DCA's Office of Human Resources (OHR), I am providing the following information for consideration by members. In 2021, the executive officer exempt level was increased to its current level E. A prior request submitted in 2017 seeking to increase the level from G to D (bypassing levels F and E) was denied by CalHR.

As part of its consideration, the Board should consider several factors including:

- Program complexity
- Program growth
- Health and safety considerations
- Salary compaction

Brief Overview of the Board and the Executive Officer Position

The Board of Pharmacy regulates all aspects of pharmacy practice in California and provides for protection of the public by overseeing approximately 140,000 pharmacy practitioners and firms through more than 32 complex regulatory programs, and the enforcement and regulatory issues arising from these programs. The Board regulates all businesses and personnel that touch drug product after it leaves the manufacturing site, until it reaches the ultimate consumer. As prescription drug distribution frequently occurs across state lines, the Board also licenses and regulates entities in other states.

The executive officer is responsible for all Board operations as well as implementing Board policies, advising the Board on critical issues, and initiating formal discipline when appropriate. Consequently, the executive officer must have demonstrated knowledge and ability to understand the pharmacy profession as well as other related businesses including drug wholesalers, hospitals, and clinics. The Board is unlike any other program or board within the DCA because of the broad spectrum of individuals, businesses, and products that the Board regulates throughout the entire drug distribution chain.

All the Board's licensees are regulated at the state level; however, because of the significant potential for consumer harm and death, Board licensees must also comply with a myriad of federal laws. Accordingly, in addition to having knowledge of California pharmacy law, the executive officer must also be conversant in the federal laws and regulations governing pharmacy practice.

Program Complexity

Pharmacy practice is a dynamic, patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes. Pharmacy practice is continually evolving to include more sophisticated and comprehensive patient care activities. Regulating such a dynamic profession results in continual changes in program complexity. It is imperative that the Board remains vigilant to ensure new state and federal laws – reflecting new practices or responding to emerging issues – are advocated for and enacted. Legislation involving licensing and enforcement activities is continually evaluated, and the Board works to secure enforcement tools necessary to effectuate consumer protection. In addition, the Legislature has in recent years directed the Board to regulate certain activities occurring outside of pharmacies, such as the redistribution of cancer medications in physician's offices, while also directing the Board to regulate workplace conditions in pharmacies, including staffing levels and workload quotas.

A summary of legislative changes since 2021 is provided below.

2021 Legislation

Board Sponsored

- SB 409 (Caballero, Chapter 604, Statutes of 2021) Pharmacy Practice: Testing

Enacted Legislation Impacting the Board

- AB 107 (Salas, Chapter 693, Statutes of 2021) Licensure: Veterans and Military Spouses
- AB 527 (Wood, Chapter 618, Statutes of 2021) Controlled Substances (Included Board-sponsored provisions)
- AB 1064 (Fong, Chapter 655, Statutes of 2021) Pharmacy Practice: Vaccines: Independent Initiation and Administration
- AB 1533 (Committee on Business and Professions, Chapter 629, Statutes of 2021) included numerous Board-sponsored provisions as part of the Sunset Review Process
- SB 306 (Pan, Chapter 486, Statutes of 2021) Sexually Transmitted Disease: Testing
- SB 310 (Rubio, Chapter 541, Statutes of 2021) Unused Medications: Cancer Medication Recycling
- SB 311 (Hueso, Chapter 384, Statutes of 2021) Compassionate Access to Medical Cannabis Act or Ryan's Law
- SB 362 (Newman, Chapter 334, Statutes of 2021) Chain Community Pharmacies: Quotas

2022 Legislation

Enacted Legislation Impacting the Board

- AB 852 (Wood, Chapter 518, Statutes of 2022) Health Care Practitioners: Electronic Prescriptions (Included Board-sponsored provision)

- AB 2194 (Ward, Chapter 958, Statutes of 2022) Pharmacists and Pharmacy Technicians: Continuing Education: Cultural Competency
- SB 731 (Durazo, Chapter 814, Statutes of 2022) Criminal Records: Relief
- SB 872 (Dodd, Chapter 220, Statutes of 2022) Pharmacies: Mobile Units
- SB 988 (Hueso, Chapter 242, Statutes of 2022) Compassionate Access to Medical Cannabis Act or Ryan's Law
- SB 1259 (Laird, Chapter 245, Statutes of 2022) Pharmacists: Furnishing Opioid Antagonists
- SB 1346 (Becker, Chapter 886, Statutes of 2022) Surplus Medication Collection and Distribution

2023 Legislation

Board Sponsored

- AB 1286 (Haney, Chapter 470, Statutes of 2023) Pharmacy
- AB 1557 (Flora, Chapter 141, Statutes of 2023) Pharmacy: Electronic Prescriptions
- SB 816 (Roth, Chapter 723, Statutes of 2023) Professions and Vocations
- SB 887 (Committee on Business, Professions and Economic Development, Chapter 510, Statutes of 2023) Consumer Affairs

Enacted Legislation Impacting the Board

- AB 317 (Weber, Chapter 322, Statutes of 2023) Pharmacist Service Coverage
- AB 663 (Haney, Chapter 539, Statutes of 2023) Pharmacy: Mobile Units
- AB 1341 (Berman, Chapter 276, Statutes of 2023) Public Health: Oral Therapeutics
- SB 345 (Skinner, Chapter 260, Statutes of 2023) Health Care Services: Legally Protected Health Care Activities
- SB 544 (Laird, Chapter 216, Statutes of 2023) Bagley-Keene Open Meetings Act: Teleconferencing

2024 Legislation

Enacted Legislation Impacting the Board

- AB 1842 (Reyes, Chapter 633, Statutes of 2024) Health Care Coverage: Medication-Assisted Treatment
- AB 1902 (Alanis, Chapter 330, Statutes of 2024) Prescription Drug Labels: Accessibility
- AB 2115 (Haney, Chapter 634, Statutes of 2024) Controlled Substances: Clinics
- SB 164 (Committee on Budget and Fiscal Review, Chapter 41, Statutes of 2024) State Government
- SB 1089 (Smallwood-Cuevas, Chapter 625, Statutes of 2024) Food and Prescription Access: Grocery and Pharmacy Closures
- SB 1451 (Ashby, Chapter 481, Statutes of 2024) Professions and Vocations
- AB 1468 (Ochoa Bogh, Chapter 488, Statutes of 2024) Healing Arts Boards: Informational and Educational Materials for Prescribers of Narcotics: Federal "Three Day Rule"

In addition to statutory changes, a number of regulation changes were also effectuated by the Board in recent years, some in part to implement legislation. (All section references below are contained in division 17 of title 16 of the California Code of Regulations.)

2021 Regulation Changes

- Amend Sections 1780, 1781, 1782, and 1783 – Drug Distributors
  Effective Date: April 1, 2021
- Amend Section 1747 – HIV Preexposure and Postexposure Prophylaxis Furnishing
  Effective Date: June 8, 2021
- Amend Sections 1702, 1702.1, 1702.2, and 1702.5 – Renewal Requirements
  Effective Date: July 1, 2021
- Amend Section 1707 – Off-Site Storage
  Effective: July 1, 2021
- Amend Sections 1711 and 1713, and Add Section 1715.1 – Automated Drug Delivery Systems
  Effective Date: July 1, 2021

2022 Regulation Changes

- Amend Section 1746.4 – Administering Vaccines
  Effective January 25, 2022
- Amend Section 1709 – Ownership, Management, and Control of Business Entity
  Effective April 1, 2022
- Amend Section 1704 – Address Change Notification
  Effective April 1, 2022
- Amend Section 1715.6 – Reporting Drug Loss
  Effective April 1, 2022
- Add Section 1717.5 – Automatic Refill Programs
  Effective Date: July 1, 2022
- Add Section 1708.1 – Notification of Temporary Closure
  Effective October 1, 2022
- Amend Section 1715 – Pharmacy/Hospital Self-Assessment Forms
  Effective October 1, 2022
- Amend Section 1784 – Wholesaler/3PL Self-Assessment Form
  Effective October 1, 2022

2023 Regulation Changes

- Amend Sections 1793.5 and 1793.6 and Add Section 1793.65 – Pharmacy Technicians
  Effective January 1, 2023
- Amend Section 1715.65 - Inventory Reconciliation
  Effective January 1, 2023
- Amend Section 1735.2 – Compounding Self-Assessment
  Effective April 1, 2023

2024 Regulation Changes

- Add Section 1706.6 – Temporary License for Military Spouses
  Effective March 21, 2024
- Amend Section 1707.6 – Notice to Consumers
  Effective July 1, 2024

- Amend Section 1732.5 and Add Section 1732.8 – Continuing Education
  Effective July 29, 2024
- Amend Section 1747 – Independent HIV Preexposure Prophylaxis Furnishing – Emergency
  Effective August 14, 2024
- Amend Section 1746.3 – Opioid Antagonist Protocol
  Effective September 17, 2024

2025 Regulation Changes

- Amend Section 1760 – Disciplinary Guidelines
  Effective January 1, 2025
- Amend Section 1749 – Fees
  Effective January 1, 2025
- Amend Section 1747 – Independent HIV Preexposure Prophylaxis Furnishing –
  Effective January 31, 2025
- Amend Section 1793.65 – Pharmacy Technician Certification Programs Documents
  Effective February 4, 2025
- Amend Section 1709.1 - Designation of Pharmacist-in-Charge
  Effective April 1, 2025
- Add Section 1700 – Digital Signatures
  Effective July 1, 2025

In addition, the Board has a number of regulations in various stages of promulgation.

- Amend Section 1708.2 – Discontinuance of Business
- Add Section 1746.6 – Medication Assisted Treatment Protocol
- Amend Section 1711 – Quality Assurance Programs
- Add Section 1750 – Outsourcing Facility Self-Assessment
- Amend Section 1713 – Automated Patient Delivery Systems Consultations
- Repeal Sections 1708.3, 1708.4, 1708.5, 1735 et seq., and 1751 et seq. and Add New Sections 1735 et seq., 1736 et seq., 1737 et seq., and 1738 et seq. – Compounded Drug Preparations

The sheer volume of statutory and regulatory changes clearly demonstrates the dynamic nature of the Board's jurisdiction and speaks to the program complexity and continual evolution and expansion of the Board's role as a consumer protection agency. The policy changes detailed above further reveal the breadth of the scope of changes that have occurred in the last several years, including expanded authority for pharmacists to provide immunizations, perform CLIA waived tests, furnish opioid reversal products, and engage in "test to treat" for the diagnosis and treatment of COVID-19. The Legislature recognizes the Board as experts in the regulation of drug distribution and has placed within the Board's authority responsibility and oversight for the redistribution of cancer medications in physician's offices and requirements for the Board to evaluate pilot projects related to the redistribution of donated medications. The Legislature also placed responsibility on the Board to register all prescribers seeking exemptions to e-prescribing requirements and charged the Board with oversight of new practice models to ensure access to prescription medications through the use of mobile pharmacies. In addition, the Legislature has passed legislation requiring the Board to begin regulating working conditions such as staffing levels within pharmacies and

workload quotas. Implementing such authority necessitates the Board obtaining and evaluating information outside of the typical drug distribution and dispensing process.

The Board is a national leader in policy development, sponsoring legislation to support access to care through population based collaborative practice agreements as it did in AB 1533 (Committee on Business and Professions, Chapter 629, Statutes of 2021) or expanding access to medication assisted treatment through sponsorship of pharmacist authority to provide MAT pursuant to a state protocol.

Notably, in 2023 the Board sponsored a comprehensive patient medication safety act, which includes among its many provisions a first in the nation mandatory reporting requirement for medication errors that occur in the outpatient setting, as well as minimum staffing requirements in specified pharmacy settings. Again, the Board established its national leadership by establishing these requirements. The Board's implementation has required the Board to thoroughly and thoughtfully maintain state and federal confidentiality requirements while ensuring development of a process to facilitate the mandatory reporting of medication errors and dissemination of critical information learned through these reports, with the focus on reducing medication errors including those that cause harm and death to patients. Once fully implemented, the Board's leadership in this area will not only impact California patients, but will have national impact. Lessons learned from this information will inform medication safety standards, could result in changes federally, development of best practices and future legislative or regulatory changes all focused on addressing consumer safety issues.

The program complexity extends far beyond the matters detailed above. The Board's executive officer position also demands a high level of political acumen. The Board's diverse licensee population includes not only individuals and small businesses, but some of America's largest companies including United Healthcare, Cigna, Cardinal Health, Cencora, Walmart, Amazon, CVS Health, and McKesson. Understanding the varying dynamics between regulating an individual licensee and corporate licensees is critical to public protection as the challenges are different.

Program Growth

Regulation of drug distribution is complex, involving a myriad of state and federal laws designed to ensure the safety and efficacy of prescription drugs. Consequently, the Board's regulatory framework is extremely complex. In addition, the Board's regulatory authority continues to expand. The Board's regulation includes highly specialized entities such as outsourcing facilities that perform large scale compounding for distribution throughout the nation, to advanced level practitioners performing direct patient care services beyond those of traditional pharmacists.

As described, the scope of practice for pharmacists continues to expand to include, among others, providing CLIA waived tests and working under collaborative practice agreements. Pharmacists now have the ability to provide patient care in a "test to treat model" for patients with COVID. In all such instances, the Board's implementation efforts must include education, and balancing enforcement activities to ensure safeguards are in place to protect consumers.

With many of these new provisions, the Board must transition away from its traditional regulation model focusing on compliance primarily with prescriptive requirements in law, to an assessment of the quality of the patient care services provided for these expanded services.

Such a transition requires extensive education of staff along with recruitment and training of experts.

Effective January 1, 2022, the Legislature has also provided the Board with extensive citation and fine authority, including the ability to issue fines of up to $100,000 for similar violations by pharmacies under common control and fines of up to $150,000 for violations stemming from either written policy or that were expressly encouraged by the common owner or manager.

In addition to regulatory growth, the Board's expenditure authority for FY 2024/25 is about $35.2 million, about 20 percent growth since FY 2020/21.

In addition to growth in authorized expenditures and in response to expansion of program growth and complexity, the Board's executive management now includes four CEA positions and four senior manager positions.

Health and Safety Considerations

Timely and consistent enforcement of pharmacy laws and regulations preserves public safety. Under the general direction of the executive officer, Board inspectors investigate consumer complaints and referrals from other governing agencies to determine violations of laws, rules, or regulations. Failure to act timely on these investigations will permit health endangering activities to occur, violating the Board's consumer protection mandate.

The Board's consumer protection mandate expands beyond completing investigations. It demands the Board exercise its full licensure and enforcement authority, including seeking revocation or other discipline necessary to remove or restrict licensees when appropriate, or the denial of licensure to entities or individuals when appropriate. For example, failure to adequately and appropriately inspect facilities that compound sterile products could result in significant patient harm or death if compromised product is dispensed to patients. All of this is achieved through the leadership and guidance of the Board's executive officer.

Health and safety considerations could be detailed for many of the legislative and regulatory changes detailed; however, to demonstrate the significant consequences, below are a few examples.

Because of the significant potential for patient harm, the executive officer has unique authority to issue a cease and desist order when the executive officer has reasonable belief based on information obtained during an inspection or investigation that preparations compounded by a pharmacy or outsourcing facility pose an immediate threat to the public health or safety. Although such authority was originally limited to sterile compounding pharmacies, this authority was expanded to extend to issuing such orders to unlicensed entities as well as outsourcing facilities. Most recently this authority was further extended to allow for the issuance of such an order if the executive officer believes conditions within a pharmacy pose an immediate threat to patients or pharmacy personnel. The executive officer has issued two such orders under this new authority, providing immediate consumer protection while remediation efforts were undertaken to resolve the unsafe conditions. The authority granted to the executive officer to secure immediate public protection without the typical provisions of due process speaks to the significant potential for public harm.

The range of responsibility and scope of potential harm is apparent for each of the Board's licensing programs. Direct patient harm ranges from delays in therapy, moderate patient harm as well as the tragic loss of life. It is important to note that the scope of potential harm ranges depending on the practice site. As an example, specific patient harm resulting from a medication error through a dispensing process at a pharmacy typically is generally limited to a single patient that received the wrong medication. However, the same is not true for compounded drug preparations from an outsourcing facility, regulated by the Board.

An outsourcing facility is an entity licensed by the Board that compounds drug preparations for mass distribution as opposed to patient specific prescriptions. Under the provisions of Pharmacy Law, such facilities engage in the compounding of sterile and nonsterile drugs consistent with current good manufacturing practice requirements (CGMP). Outsourcing facilities vary in terms of size and drug products. Because of the inherent risks involved in compounding drug preparations, most notably sterile preparations that are typically injected, inhaled or used in a patient's eye, such facilities must be closely regulated to ensure compliance with CGMPs, best practices and provisions of Pharmacy Law to ensure potential risks to patients are quickly identified and remedied. By nature of their business, outsourcing facilities generally mass produce compounded drug preparations and sell the products nationwide. For example, a batch of compounded preparation could be distributed to hospitals throughout California. Should a batch be contaminated, its implications for patient harm are far reaching. Regrettably, the national distribution of contaminated product has occurred in the past, in one instance resulting in significant injury to over 750 patients and deaths of about 80 patients. In another instance, patients were blinded by the use of the contaminated product.

The risks associated with compounding preparations and the significant rise in the compounding of sterile preparations cannot be overstated. The continued evolution of compounding practices, whether in IV hydration or weight loss drugs (such as GLP-1s), reinforce the importance of appropriate oversight focusing on consumer safety.

The Board routinely navigates cross jurisdictional issues and advocates on behalf of California consumers at the national level given the Board's broad regulatory authority over the drug supply chain. As an example, such a dynamic is very pronounced in the Board's regulation of outsourcing facilities previously described, where the Board routinely coordinates its efforts with the federal Food and Drug Administration and the federal Drug Enforcement Administration.

Salary Compaction

Salary compaction is another factor for consideration by the Board. Salary compaction occurs when a supervisor's maximum salary is less than 5% above the maximum salary of their highest-paid subordinate. To address this, CalHR may adjust salary ranges, add salary steps, or increase the salary plan/grade. The goal is to maintain a minimum 5% pay differential.

For purposes of illustration, the chart below presents the current salary ranges for the Board's executive officer, deputy executive officer, and chief of enforcement positions:

Position	Level	Salary
Executive Officer	Exempt level E	$14,374
Deputy Executive Officer	CEA Level B	$14,032
Chief of Enforcement	CEA Level A (Salary Consideration)	$14,032

The EO's current salary is at the top of the range listed above. As illustrated above, the top of the salary range for both the deputy executive officer position and the chief of enforcement position is only about 2.5% less than the top of the range for the EO position.

Based on significant increase in the level of complexity, significant changes in jurisdiction and authority, and salary compaction issues, it may be appropriate for the Board to consider a change in the exempt level and salary for the executive officer.

Accomplishments

1. Collaborated with members on the development and successful passage of a comprehensive legislative proposal establishing significant patient protections including establishing and implementing first the nation requirements. Provisions included:
   a. Establishing a first in the nation medication error reporting requirement.
   b. Expanding the authorized duties for pharmacy technicians.
   c. Establishing minimum staffing requirements.
   d. Establishing a self-assessment process for surgical clinics.
   e. Establishing cease and desist authority where unsafe conditions exist within pharmacies.
2. Collaborated with members on the completion of the Board's legislative Sunset Report that included the develop of significant policy proposals. The significant policy proposals included in the legislative measure, Assembly Bill 1503 (Berman, 2025). A few of the significant policy proposals developed and incorporated into the measure include:
   a. Improving oversight of nonresident pharmacies including establishing authority to inspect such facilities and establishing new requirements for licensure of personnel responsible for oversight and operational compliance of such pharmacies.
   b. Expand authority for pharmacy technicians to perform specified services outside of pharmacies.
   c. Increase citation and fine authority for mail order pharmacies. These citations and fines are assessed by the executive officer.
   d. Establishing new provisions to address provisions for pharmacy deserts.
   e. Transition pharmacist practice to a standard of care practice model.

Recommendation: President Oh recommends the Board consider a change in the exempt level designation for the executive officer position from level E to level "none," increase the salary maximum range by up to 10%, and increase the salary of the current executive officer by up to 10%.

Possible Motion:

> Delegate to the Board President to submit requests to the Department of Consumer Affairs and CalHR to (1) change the exempt level of the Board's executive officer (EO) position to "none"; (2) specify a salary range for the EO position with a monthly

minimum equal to the EO's current monthly salary and a monthly maximum equal to the current monthly salary plus up to 10%; and (3) increase the monthly salary of the current executive officer to an amount equal to the current monthly salary plus up to 10%.