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Per California Code of Regulations, title 2, section 548.5, the following information will be posted to CalHR's Career Executive Assignment Action Proposals website for 30 calendar days when departments propose new CEA concepts or major revisions to existing CEA concepts. Presence of the department-submitted CEA Action Proposal information on CalHR's website does not indicate CalHR support for the proposal.

	A. GENERAL INFORMATION
1. Date	2. Department
2025-09-30	Department of Health Care Access and Information
3. Organizationa	al Placement (Division/Branch/Office Name)
Office of Health	Care Affordability / Pharmaceutical Policy and Programs Branch
4. CEA Position	Title
Assistant Deputy	Director for Pharmaceutical Policy and Programs Branch
5. Summary of p (2-3 sentences)	proposed position description and how it relates to the program's mission or purpose.
and Programs B access and affor which enables the analysis and development directly support through a more	eputy Director for Pharmaceutical Policy and Programs leads the Pharmaceutical Policy tranch, driving strategic partnerships and innovative policy solutions to improve medication redability in California. The role executes strategic partnerships under the CalRx program, ne state to produce and distribute low-cost medications, and oversees research, data velopment of recommendations for policymakers in public reports. These responsibilities HCAl's mission by promoting equitable access to affordable, high-quality health care equitable, transparently priced pharmaceutical market where all Californians can afford medicines they need.
6. Reports to: (C	Class Title/Level)
CEA B, Deputy	Director
7. Relationship v	with Department Director ( <i>Select one</i> )
	department's Executive Management Team, and has frequent contact with director on a of department-wide issues.
	er of department's Executive Management Team but has frequent contact with the anagement Team on policy issues.
Mana	nember of the OHCA leadership team, the Assistant Deputy Director will work very closely with the Deputy Director and HCAI's Executive gement team to develop and implement new pharmaceutical programs and policies that improve affordability and access for rnians.
8. Organizationa	al Level (Select one)
☐ 1st ☐ 2nd	✓ 3rd ☐ 4th ☐ 5th (mega departments only - 17,001+ allocated positions)

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#### **B. SUMMARY OF REQUEST**

9. What are the duties and responsibilities of the CEA position? Be specific and provide examples.

The Assistant Deputy Director for Pharmaceutical Policy and Programs will lead the Pharmaceutical Policy and Programs Branch (PPPB) of the Office of Health Care Affordability (OHCA) and report directly to the Deputy Director. Established with the enactment of the 2022-23 state budget, OHCA will provide a comprehensive view of health care spending, cost trends, and variation to inform actions to reduce the overall rate of growth in health care costs while maintaining quality of care, with the goal of improving affordability, access, and equity of health care for Californians. This position has an inherently high consequence of error due to its visibility and level of decision-making for HCAI. Decisions made in this position have a critical impact on HCAI's programs and external stakeholders.

The Assistant Deputy Director will oversee all associated programmatic functions for developing strategic partnerships and innovative policy solutions to increase transparency and improve affordability in the pharmaceutical sector. They will manage the production of high quality, objective research and analysis needed to fulfill the program mission of improving equitable access and affordability of medications in California. This includes building and developing a team comprised of managers and staff capable of analyzing pharmaceutical policies, performing data analysis, conducting policy research and development. As part of strategic partnership activities, the Assistant Deputy oversees administration of the CalRx program (Pan, SB 852, Chapter 207, Statutes of 2020), which empowers the State of California to develop, produce, and distribute generic and biological drugs and sell them at low cost.

The Assistant Deputy will also, at the request of or on behalf of the OHCA Deputy Director, represent HCAI in matters relating to OHCA to the Legislature, other state, federal and local agencies, statutorily established boards, commissions, and advisory bodies to HCAI, affected constituency groups and stakeholders. They will also support responses to inquiries by the media and other interested parties concerning OHCA's role in reporting public information about the pharmaceutical sector.

The Assistant Deputy will be primarily responsible for the following activities related to the pharmaceutical sector: a) executing strategic partnerships for improving drug affordability and access that include development, production, acquisiton, and/or distribution of generic and biological drugs at low cost, including the CalRx Biosimilar Insulin Initiative, CalRx Naloxone Access Initiative and other target drug initiatives; b) supporting OHCA's implementation of spending targets, including public reporting of spending trends, cost drivers, and variation as it relates to pharmaceuticals and evaluation of high-cost drugs as a potential factor for exceeding spending targets; and c) research and analysis on the pharmaceutical sector, including data analysis and research, assessment of access barriers and other impacts of intermediaries, review of best practices in other states that make drugs more affordable and accessible and development of policy recommendations on the pharmaceutical sector in public reports.

For example, implementing each of the CalRx strategic partnerships requires the Assistant Deputy to lead significant policy-related actions, including research and analysis pertaining to legal, market, policy and regulatory factors impacting access to affordable drugs, including but not limited to drug development, federal Food and Drug Administration regulatory approval processes, and supply chain and distribution channels. In overseeing the CalRx Biosimilar Insulin Initiative, the Assistant Deputy will monitor the State's \$50 million dollar investment in developing biosimilar versions of the three most popular insulin medications; one long-acting and two rapid-acting products – glargine, aspart, and lispro, respectively, in both vial and pen form. Insulin has been a significant financial burden for Americans., and the work of CalRx will help make these essential medicines available at a fraction of existing cash prices. The Assistant Deputy will provide oversight of the selected contractor in promoting the broad availability of these products in retail pharmacies, and other channels, such as mail order pharmacy.

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# B. SUMMARY OF REQUEST (continued)

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10. How critical is the program's mission or purpose to the department's mission as a whole? Include a description of the degree to which the program is critical to the department's mission.	
✓ Program is directly related to department's primary mission and is critical to achieving the department's goals.	
☐ Program is indirectly related to department's primary mission.	
☐ Program plays a supporting role in achieving department's mission (i.e., budget, personnel, other admin functions).	
Plescription: HCAI's mission is to expand equitable access to health care for all Californians, ensuring every community has the health workforce they need, safe and reliable health care facilities, and health information that can help make care more effective and affordable. Specifically, our Office of Health Care Affordability (OHCA) seeks to improve health care affordability through data analysis of health care spending data and holding health care entities to spending targets. Understanding the nuances of the complex pharmaceutical sector is critical for OHCA's implementation of spending targets, specifically in assessing the extent of control health care entities have in managing growth in drug spending, and research and analysis the informs recommendations for state policymakers. OHCA also administers the CalRx program which provides generic drugs at a low, transparent price. The program works to enhance competition in the pharmaceutical market by addressing areas with limited competition, drug shortages, and vulnerable supply chains. CalRx's vision is an equitable, transparently priced pharmaceutical market where all Californians can afford and access the medications they need for healthy lives.  The Assistant Deputy Director of Pharmaceutical Policy and Programs Branch, within OHCA will directly impact, lead and support the mission of the department by providing strategic planning, directing and oversight of pharmaceutical policies and programs. The Assistant Deputy Director will oversee and implement CalRx drug affordability and access initiatives the include the development, production, acquisition, and/or distribution of generic and biological drugs at low cost. Because the pharmaceutical sector is opaque, where drug pricing is often obscured by markup behavior of intermediaries along the supply chain, the Assistant Deputy's leadership and direction will help bring much needed transparency for the public.	
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# **B. SUMMARY OF REQUEST (continued)**

11. Describe what has changed that makes this request necessary. Explain how the change justifies the current request. Be specific and provide examples.

Since its initial authorization in 2020 under SB 852 (Chapter 207, Statutes of 2020), the CalRx program has experienced significant growth in scope and complexity, creating a clear need for executive-level leadership. CalRx was originally established to improve access to essential prescription drugs and address affordability, and the Legislature has continued to support its expansion through targeted appropriations.

Following the initial \$50 million appropriation for the CalRx Biosimilar Insulin Initiative, HCAI was appropriated \$25 million in the 2023 Budget Act (Chapter 52, Statutes of 2023) for the CalRx Naloxone Access Initiative, directly supporting Governor Newsom's Master Plan for Tackling the Fentanyl and Opioid Crisis, which emphasizes equitable access to life-saving opioid overdose reversal medications. In 2025, the Budget Act (Chapter 48, Statutes of 2025) provided \$7.4 million for the CalRx Diaper Access Initiative and \$5 million for the CalRx School Albuterol Access Initiative. The FY 2025 Budget Act also expanded CalRx's statutory authority to pursue partnerships for vaccines, medical supplies, and medical devices, further increasing program complexity and impact.

The Office of Health Care Affordability (OHCA) is entering a new phase focused on analyzing total health care spending. Its statutory mandate explicitly directs the office to study the impact of prescription drug prices, assess market failures in the pharmaceutical sector, and provide policy recommendations to improve affordability. OHCA is now conducting more detailed analyses of drug utilization, pricing trends, and the role of intermediaries such as pharmacy benefit managers. This work aligns with legislative intent and supports public transparency, ensuring that policies address cost, quality, and accessibility.

The rapid expansion of programs, combined with highly visible legislative and executive priorities, has created a workload and policy oversight requirement that cannot be managed at existing levels. A CEA position is necessary to provide executive-level leadership, ensure coordinated implementation of multiple initiatives, guide multidisciplinary teams, oversee data analysis, and provide evidence-based policy recommendations to state decision-makers. This position ensures CalRx and OHCA initiatives are executed in alignment with legislative intent, the Master Plan, and broader public health goals, maximizing both policy impact and public benefit.

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#### C. ROLE IN POLICY INFLUENCE

- 12. Provide 3-5 specific examples of policy areas over which the CEA position will be the principle policy maker. Each example should cite a policy that would have an identifiable impact. Include a description of the statewide impact of the assigned program.
- 1. Executing CalRx Strategic Partnerships: The Assistant Deputy Director will have significant policy influence on CalRx target drug initiatives that improve drug affordability and accesss, including overseeing research and analysis pertaining to legal, market, policy and regulatory factors impacting access to affordable drugs, including but not limited to drug development, federal Food and Drug Administration regulatory approval processes, and supply chain and distribution channels. The Assistant Deputy will guide and direct the prioritization of target drugs, including the use of several public health and pharmaceutical market criteria, such as high consumer out-of-pocket spending, high price per unit, vulnerable target population, and evidence that a new market entrant would help resolve the problem. Drugs selected for CalRx intervention have a significant statewide impact. For example, overall naloxone prices declined by 22% in a single quarter immediately following CalRx market entry, suggesting that leveraging states' substantial purchasing power to negotiate lower prescription drug prices can have immediate market impact. To date, CalRx naloxone has saved the state nearly \$30 million since May 2024.
- 2. Supporting OHCA Implementation of Spending Targets: Because of the highly specialized nature of the pharmaceutical sector, the Assistant Deputy will lead OHCA's public reporting of spending trends, cost drivers, and variation as it relates to pharmaceuticals and evaluation of high-cost drugs as a potential factor for exceeding spending targets. The Assistant Deputy will give direction and leadership to staff leveraging data from HCAI's Healthcare Payments Data (HPD) Program to analyze drivers impacting drug spending, including but not limited to prices, utilization and new entrants. As part of OHCA's implementation of spending targets, high cost drugs may be considered by OHCA in determining whether a health care entity that exceeds the target advances to steps in the enforcement process that include performance improvement plans and financial penalties. The Assistant Deputy will recommend to OHCA senior leadership policies and procedures for considering the extent to which health care entities have control over drug spending and evaluating excessive markup of drug prices by entities.
- 3. Research and Analysis on the Pharmaceutical Sector: The Assistant Deputy will oversee research and analysis on the pharmaceutical sector, assessment of access barriers and other impacts of intermediaries, review of best practices in other states that make drugs more affordable and accessible and development of policy recommendations on the pharmaceutical sector in public reports. As part of OHCA's work to contextualize health care spending, the Assistant Deputy will oversee research and analysis of the pharmaceutical sector that considers multiple and systemic drivers of high costs, including research and development costs, the role of rebates, opaque pricing, market concentration, anticompetitive practices, and the entry of new therapeutics, such as cell and gene therapies. Additionally, as part of assessing the impacts of intermediaries in the drug supply chain, the Assistant Deputy will recommend state level policies to increase transparency of drug prices, address inflation of drug prices, and reform practices of entities, such as pharmacy benefit managers. These recommendations may be included in highly visible reports by OHCA as part of its obligations to publicly report on health care spending and recommendations for further action by state policymakers.

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## C. ROLE IN POLICY INFLUENCE (continued)

## 13. What is the CEA position's scope and nature of decision-making authority?

The Assistant Deputy Director (ADD) plans, directs, and oversees CalRx and OHCA pharmaceutical policy and program initiatives, providing executive leadership with direct impact on statewide health policy and public outcomes. The ADD serves as the administrative lead of the Pharmaceutical Policy and Programs branch, exercising authority to implement statutory responsibilities and make decisions that shape program operations and statewide policy.

The ADD's authority is grounded in: SB 852 (Chapter 207, Statutes of 2020): Establishing CalRx and authorizing initiatives to improve access and affordability of generic and biologic drugs. AB 1130 (Chapter 143, Statutes of 2021): Directing OHCA to analyze health care spending trends, including pharmaceuticals, and develop policy recommendations. Budget Act appropriations: One-time funding for CalRx initiatives, including the Biosimilar Insulin Initiative (FY 2020–21), Naloxone Access Initiative (FY 2023–24), Diaper Access Initiative (FY 2025–26), and School Albuterol Access Initiative (FY 2025–26), enabling program implementation in alignment with legislative intent.

The ADD has decision-making responsibility for: Program and policy oversight: Directing the design, implementation, and evaluation of all CalRx target drug initiatives and pharmaceutical programs. Resource and personnel management: Hiring and supervising staff to carry out research, data analysis, and program operations. Policy development: Conducting research on pharmaceutical utilization, costs, and access barriers; assessing intermediaries and best practices; and developing evidence-based policy recommendations that inform statewide strategies. Strategic partnerships: Authorizing and managing collaborations for drug acquisition and distribution, ensuring initiatives that advance public health goals, including Governor Newsom's Master Plan for Tackling the Fentanyl and Opioid Crisis. Through this statutory authority and executive discretion, the ADD makes independent decisions that directly shape program direction, pharmaceutical policy, and public health outcomes, ensuring legislative intent is achieved and statewide policy goals are advanced.

# 14. Will the CEA position be developing and implementing new policy, or interpreting and implementing existing policy? How?

The Assistant Deputy Director (ADD) will have executive-level responsibility for both developing new pharmaceutical policies and implementing existing statutory programs, exercising independent judgment in shaping statewide strategies for OHCA and CalRx.

The ADD will develop new policy by leading the design of new CalRx target drug initiatives, recommending strategies to address pharmaceutical affordability, and proposing programmatic approaches to emerging health needs. Policy development will include analyzing spending trends, assessing market dynamics, evaluating intermediaries such as pharmacy benefit managers, and reviewing best practices from other states. The ADD will implement existing statutory programs by overseeing the execution of legislatively authorized initiatives, ensuring alignment with statutory intent and legislative appropriations. The ADD will establish operational guidelines, direct program staff, and monitor performance to ensure that CalRx and OHCA objectives are met. The ADD will inform and shape policy decisions by participating in legislative analysis, budget change proposals, and programmatic reporting; they will coordinate with other state departments, industry stakeholders, health care entities, and advocacy organizations; and provide recommendations directly to OHCA senior leadership and state policymakers.

Through these responsibilities, the ADD exercises executive level authority, making decisions that directly shape both program implementation and statewide pharmaceutical policy. This includes determining operational approaches, prioritizing initiatives, and recommending policy interventions that improve access, affordability, and public health outcomes.