

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

6/20/2024

2. Department

California Department of Public Health

3. Organizational Placement (Division/Branch/Office Name)

Center for Environmental Health/Division of Food and Drug Safety

4. CEA Position Title

Chief, Division of Food and Drug Safety

5. Summary of proposed position description and how it relates to the program's mission or purpose.
(2-3 sentences)

This position supports the California Department of Public Health's (CDPH) mission and strategic plan by managing and directing policy and program development on a wide range of public and environmental health issues. The CEA B, Chief, Division of Food and Drug Safety (DFDS), including the Food and Drug Branch (FDB) and Office of Youth Tobacco Enforcement (OYTE), serves as the liaison with other state entities for food, drug, medical device, and tobacco enforcement issues, including the California Health and Human Services Agency (CalHHS/Agency), the Department of Food and Agriculture (CDFA), Department of Fish and Wildlife, Office of Health Hazard Assessment within Cal/EPA, as well as with the Governor's Office, the Legislature and with California business and health care communities. The CEA coordinates with federal and local governmental entities addressing food, drugs, medical devices, and tobacco enforcement. This request is to update the existing CEA concept for the Chief based on recent organization changes within the Department and DFDS.

6. Reports to: (Class Title/Level)

Deputy Director, CEA C, Center for Environmental Health

7. Relationship with Department Director (Select one)

- ☒ Member of department's Executive Management Team, and has frequent contact with director on a wide range of department-wide issues.
- ☐ Not a member of department's Executive Management Team but has frequent contact with the Executive Management Team on policy issues.

(Explain): Attends all Public Health Executive Management Team meetings; discusses policy issues, recommendations, and outcomes with Director and executive management team.

8. Organizational Level (Select one)

☐ 1st ☐ 2nd ☒ 3rd ☐ 4th ☐ 5th (mega departments only - 17,001+ allocated positions)

B. SUMMARY OF REQUEST

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

The Division Chief is responsible for the DFDS and provides professional management, expertise, and general administrative leadership in the control and prevention of food borne illness and health fraud, safety of drugs and medical devices. The Division Chief develops statewide policies, standards, and regulations that provide the programmatic guidance and direction for the DFDS. For example, the Division Chief, DFDS developed statewide policies to ensure over 35,000 licensed tobacco retailers in California are periodically reviewed for compliance with age-related laws for tobacco products. These policies serve as a guide for the OYTE when generating annual work plans for conducting undercover sting operations, and follow-up enforcement for violations. They also ensure the safety of officers and volunteer underage decoys as they conduct sting operations and enforcement work. The Division Chief plans, organizes, directs and manages staff within the FDB, which regulates California's food, drug and medical device manufacturers and industrial hemp manufacturers. The OYTE enforces age-related tobacco laws and reduces underage exposure to tobacco products across the state.

The Division Chief devises long-term division goals and objectives that are essential to protecting and regulating California's food, drug, medical device, and industrial hemp industries, as well as prevent health fraud related to home medical device retailers selling unlicensed and unsafe home medical device equipment. The Division Chief reviews existing and proposed policies, proposed regulations, contracts, and human resource plans for appropriateness. The Division Chief also reviews and provides input for legislative analyses, reports, and proposed regulations from the standpoint of adherence to CDPH policy on proposed legislative direction, in particular with the development of the newly established industrial hemp program within FDB as well as the newly created OYTE. For example, the Division Chief leads policy updates to address the addition of specific flavored tobacco enforcement as authorized under AB 935 (2023 legislative session).

The Division Chief consults with local health officers, directors of environmental health, U.S. Department of Homeland Security, U.S. Food and Drug Administration, U.S. Department of Agriculture, Governor's Office of Emergency Services, California Department of Food and Agriculture, the Department of Consumer Affairs, Department of Cannabis Control, Office of Environmental Health Hazard Assessment, and others in preparing statewide policies on foods, drugs, medical devices, industrial hemp products, and underage tobacco enforcement.

The Division Chief evaluates food, drug, medical devices, health fraud, industrial hemp, and underage tobacco enforcement methods to determine their effectiveness in the control and prevention of illness, protection of public health, and compliance with established laws, and makes recommendations for improvement to ensure methods are effective and updated in accordance with state-wide policies and procedures. The Division Chief provides professional review of various technical and other reports to the legislature to ensure compliance with departmental policies and legislative requirements.

The CEA develops policies for food, drug and cosmetic safety in California. The DFDS oversees manufacturing, holding/storage, processing, and distribution of products from these industries. These policies impact the health and safety of every resident that consumes or uses one of these products (essentially all Californians), as well as consumers across the nation and the world. This includes developing training and regulatory policies, along with specific policies to coordinate and implement investigations and timely responses to illness outbreaks associated with any of the products regulated by DFDS programs. Specific policies cover field inspections, tracebacks to find source product, recalls and embargoes, and compliance and enforcement actions. Effective and relevant policies are important not only for public health and protection, but also for the regulated industries in order to ensure safe adequate supplies of essential products, a safe workplace, and economic stability.

The Division Chief develops policies ensuring drugs and medical devices are in compliance with federal and state laws and are safe, effective, and legal to offer for sale. This helps to reduce risk to consumers and risk of health fraud to consumers who may purchase counterfeit or ineffective products. Additionally, the Chief provides key policy guidance and direction around reviewing existing standards and modifying or creating newer ones as needed. The most recent example of this is current efforts to implement policies for Industrial Hemp in foods, beverages and cosmetics (resulting from AB 45 which legalized such products in California).

The Division Chief serves as the State's spokesperson on all issues that relate to food, drugs, medical devices, health fraud, and industrial hemp products and, as needed, on the enforcement of underage tobacco use; keeps current in the latest developments and research; represents the State on these issues at federal, state, and local meetings; and responds to emerging issues by routinely informing the administration and program staff of policy implications and by recommending appropriate responses. Policies relating to these issues directly impact California's 61 local health jurisdictions and may impact national public health policy.

B. SUMMARY OF REQUEST (continued)

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).

Description: CDPH's mission is to optimize the health and well-being of the people of California. The DFDS serves a key component of this mission by administering programs that protect and manage food, drugs, medical devices and industrial hemp manufacturing. DFDS also conducts emergency response, surveillance and assessment, and technical assistance activities to benefit the public and regulated entities. DFDS administers a highly specialized enforcement program with the mission to reduce underage tobacco use and combat underage exposure to addictive tobacco products.

The DFDS, led by the Division Chief, collaborates with other public health programs across the department, and many other state agencies along with federal/national partners, local environmental health entities and other stakeholders, in order to best address complex public health challenges associated with foods, drugs, medical devices, industrial hemp, and tobacco enforcement.

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.

This request is to document major changes to the DFDS CEA concept related to reorganizations that have taken place over the last several years.

In early 2018, the Association of Public Health Laboratory recommended the Department consolidate multiple existing laboratories into the newly created Center for Laboratory Sciences (CLS) to promote efficiencies and improve overall effectiveness of operation and services. Upon consolidation in 2022, 34 authorized positions within the Food and Drug Laboratory Branch transitioned to the new CLS. During the same period DFDS gained 9 tobacco enforcement positions with the passage of AB 935 (2023 legislative session) and 25 new positions and funding with the approval of AB 45 industrial hemp program (Chapter 576, 2021). Also concurrent with the move of the Food and Drug Laboratory Branch, the Department approved a reorganization within DFDS to move the existing tobacco enforcement program from FDB to establish the OYTE, thereby creating an additional office within the Division organizational structure. The addition of both the Industrial Hemp (IH) program and flavored tobacco enforcement has significantly changed the scope and breadth of the Division Chief's responsibilities.

DFDS is now comprised of the FDB with 171.5 authorized positions and a budget of \$40 million, and the OYTE with 61 authorized positions and a budget of \$13 million, for a total of 232.5 authorized positions and a budget of \$53 million dollars. As mentioned, the tobacco program was an existing, authorized program with 61 staff working within FDB focused on statutorily-mandated age-related tobacco enforcement across the state. DFDS, with the approval of the Department, moved the existing tobacco enforcement positions and support staff out of FDB and into a new office (OYTE). This change benefited a large branch struggling with span-of-control by reducing their total number of positions and workload, thereby allowing better focus on food, drug, and medical device safety. The tobacco enforcement programs operate more efficiently by allowing direct oversight of policies, positions, budget, and enforcement at the Division level. These changes better serve our external and internal stakeholders and support the critical work of reducing addiction to nicotine and tobacco products in youth.

The scope and breadth of this CEA position has increased with the the passage of AB 935 (2023 legislative session) authorizing flavored tobacco enforcement. The Division Chief is responsible for the oversight, development, and updates of highly-sensitive policies for underage tobacco enforcement of over 35,000 licensed tobacco retailers across the state. These retailers require periodic checks for compliance of age-related laws for tobacco products. With the passage of AB 935, the legislature authorized the Department to significantly increase it's state-wide tobacco enforcement scope to include flavored tobacco products. This is expected to bring in over \$2.2 million dollars to fund an additional 9 positions. Existing policies will require updates to include this new, highly sensitive enforcement scope and serve as a guide for the OYTE when generating annual work plans for conducting undercover sting operations and flavored tobacco enforcement at tobacco retailers across the state. Due to an increase in questions from local health jurisdictions, along with increased media-attention, the legislature has greatly increased their attention to flavored tobacco enforcement. The addition of flavored tobacco enforcement has a high consequence of error should enforcement not be effective, potentially resulting in increased youth exposure to tobacco, increased rates of addiction and smoking-related illnesses and deaths, and an inequitable and disproportionate effect on socio-economic groups targeted with flavored tobacco products.

In 2021, the Department initiated the IH Oversight and Enrollment program under the direct oversight of the Division Chief, with 25 new positions and a mandate to license, inspect, and bring into compliance the statewide manufacture of foods and cosmetics with approved IH ingredients. The Division Chief was charged with the responsibility of ensuring policies related to the standing up and administration of the new program are established, including the development of regulations to authorize licensing and fee requirements; establishment of structures and processes; development of outreach and educational materials to inform stakeholders and the legislature of the new requirements; and addressing frequently asked questions. Due to the nature of cannabinoids and the potential for intoxication if not properly regulated, this program has become highly sensitive to media and stakeholder attention. The proliferation of illegal, unlicensed IH products that contain intoxicating cannabinoids pose a direct threat to public health. This threat has exponentially increased the consequences of error if left unchecked and unregulated, as it has and may continue to result in deaths and illnesses.

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.

The Division Chief will be the primary policy maker in the following specific public health domains, including these examples:

Food, drug, and cosmetic safety: California is home to thousands of licensees that manufacture, hold/store, process, and distribute products from these industries. Combining the complex science into a comprehensive set of licensing, inspection and compliance, and remediation policies, the Division Chief plays a critical role to ensure these products are manufactured safely for every resident that consumes or uses one of these products (essentially all Californians), as well as consumers across the nation and the world. This includes developing training policies related to effective licensing, inspection, and enforcement work, and regulatory policies to ensure laws and regulations remain updated and relevant to an ever-changing environment. Specific training policies cover field inspections, tracebacks to find source product, recalls and embargoes, and compliance and enforcement actions. The Division Chief provides key policy guidance and direction around reviewing existing regulations or standards, and modifying or creating new regulations as needed.

Industrial Hemp (IH): The Division Chief leads the development of policies for effective regulation, licensure, inspection and compliance, and enforcement for the addition of IH extracts into human food, beverages, cosmetics, and pet foods. Increasing instances of illegal products in the marketplace have resulted in illnesses and deaths, an increasing trend of emergency room visits, and increased reports of exposure to children from products made from unregulated industrial hemp extracts. The Division Chief oversees the development and updates of emergency regulations to have both age-restrictions and maximum levels of intoxicating cannabinoids in products to rapidly mitigate these significant risks to public health. The Division Chief is intimately involved in the development of internal compliance and enforcement policies and work plans, and local health department guidance documents related to compliance and enforcement, working directly with the Governor's Office and Health and Human Services Agency. The statewide impact of these rapidly evolving policies are to ensure regulated IH products are safe, exposure is limited to over age 21, and products do not have intoxicating levels of cannabinoids, protecting the overall health of the public.

Safe seafood: The Division Chief works with multiple internal and external state and federal partners on developing guidelines and implementing state-wide standards to ensure the safety of seafood harvested from California's coastal waters. These policies are critical to protect the public from potential hazards from consuming shellfish or finfish and include bacterial, viral, parasitic pathogens or chemical toxins that may be natural (e.g. algal bio-toxins) or due to human activity (e.g. sewage or runoff or heavy metals and pesticides). Weaving together the complex science associated with the detection of these hazards, in conjunction with the potential health risks from exposure, the Division Chief oversees the development of inspection, compliance, sampling, and enforcement policies to help reduce the risk to consumers. The Division Chief also oversees the development of new regulatory policies that update and adapt shellfish sanitation requirements, fees, and record keeping requirements to keep pace with the ever-changing environment. The impacts are statewide in coastal harvesting areas and with seafood processors state-wide, and consumers nationwide and worldwide. The reach of these policies can involve diverse communities and demographics, including tribal and subsistence fishing and recreational use.

Underage tobacco enforcement: The Division Chief plays a key role in providing guidance and oversight on developing or updating policies for underage tobacco enforcement across the state. There are over 35,000 licensed tobacco retailers in California that require periodic checks to determine if they are in compliance with age-related laws for tobacco products. These policies serve as a guide for the OYTE when generating annual work plans for conducting undercover sting operations, and follow-up enforcement for retailers. They also ensure the safety of officers and volunteer underage decoys as they conduct sting operations and enforcement work. Additionally, the Division Chief leads efforts to update these policies and the annual work plans to incorporate specific flavored tobacco enforcement as authorized under AB 935 (2023 legislative session). Ensuring policies are updated and in compliance is essential to the OYTE, which enforces age and flavor tobacco laws to reduce underage exposure to tobacco products across the state.

Sworn peace officer/investigator: The DFDS houses the only two programs in the Department that utilize sworn peace officers for conducting authorized investigations and enforcement. The Division Chief, working with the Office of Legal Services and the Human Resources Division, serves as the lead on reviewing, updating, and finalizing specific, highly-sensitive policies for the sworn peace officers conducting investigation and enforcement work within DFDS. These policies must align with statewide statutory authorities and mandates for sworn peace officers, as well as meet applicable POST regulations. Examples of policies the Division Chief is directly responsible for include the department's Firearms Policy, Use of Force Policy, and Chemical Agent/Oleo-resin Capsicum (OC) Policy. These policies impact all enforcement operations statewide, ensuring all sworn staff are trained to operate safely, equitably, and in compliance with state laws to protect themselves, the public, and the stakeholders with whom they engage.

C. ROLE IN POLICY INFLUENCE (continued)

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

The Division Chief has authority over key statewide environmental public health policies and regulatory programs that maintain an environment that contributes positively to health, prevents illness, and assures protection of the public. Specifically, the DFDS' programs protect and manage food, drugs, and medical devices, including industrial hemp manufacturing, and reduce youth tobacco initiation and use by enforcing California's prohibition of underage sales of tobacco products and flavored tobacco products.

As a result, the Division Chief's position scope and nature of decision-making authority involve highly sensitive, controversial, and scientifically complex issues that are statewide and may involve federal agencies, other state entities and local agencies. The Division Chief has delegated decision-making authority regarding the implementation of policies and the strategies and methods by which information will be disseminated and work will be performed by programs, including decisions pertaining to program and budget/funding priorities, and legislative needs and guidance. The Division Chief reports directly to the Deputy Director for CEH (CEA-C) and provides regular updates to the Deputy Director, Assistant Deputy Director, Director, Agency Secretary, and Governor's Office regarding decisions, strategies, and development/implementation of DFDS activities and methodologies. The decisions made by the Division Chief have a substantial impact not only on the department, but also on external stakeholders, the California population-at-large, and anyone who consumes or uses products produced by DFDS licensed facilities nation-wide and world-wide.

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

The Chief will be developing and implementing new policy and evaluating and revising existing policies as needed. This position directly addresses a myriad of scientific and technical issues that directly relate to interpreting and updating existing policy of the branches within the Division, as described above. New policies requiring development and implementation are often driven by legislative and budgetary changes. The Chief must anticipate new challenges stemming from federal agency directives that may not align with existing State policies. In this capacity, the Chief will be required to thoroughly investigate, analyze, and engage with affected groups to determine if the policy adheres to the principles of public health protection and safety. Typically, policy development involves the development of laws, rules, and regulations, which serve as the foundation for enforcing these changes.