AGENDA

ASSEMBLY BUDGET SUBCOMMITTEE NO. 6 ON BUDGET PROCESS, OVERSIGHT AND PROGRAM EVALUATION AND ASSEMBLY COMMITTEE ON GOVERNMENTAL ORGANIZATION

ASSEMBLYMEMBERS PHIL TING, ADAM GRAY, CHAIRS

TUESDAY, NOVEMBER 10, 2020
9:30 A.M., STATE CAPITOL, ASSEMBLY CHAMBER

We encourage the public to provide written testimony before the hearing. Please send your written testimony to: BudgetSub6@asm.ca.gov. Please note that any written testimony submitted to the committee is considered public comment and may be read into the record or reprinted.

*Due to the statewide stay-at-home order and guidance on physical distancing, seating for this hearing will be very limited for press and for the public. All are encouraged to watch the hearing from its live stream on the Assembly's website at **https://www.assembly.ca.gov/todaysevents**.*

The Capitol will be open for attendance of this hearing, but the public is strongly encouraged to participate via the web portal, or one of the Remote Testimony Stations available for testimony throughout the state (see locations below).

1. *Oakland – Elihu M. Harris, State Office Building (1515 Clay Street, Oakland, CA 94612)*
2. *Fresno – Hugh Burns State Building (2550 Mariposa Street, Fresno, CA 93721)*
3. *Los Angeles – Ronald Reagan State Building (300 South Spring Street, Los Angeles 90013)*
4. *San Diego – State Building (1350 Front Street, San Diego, CA 92101)*

Informational Hearing

An Update on California's Response to the COVID-19 Pandemic: *An overview of the State's operational efforts to contain the pandemic, investing emergency disaster funds, preparations for distributing a vaccine and procuring personal protective equipment for Californians.*

I. **Introduction from Chair and Members**

II. **Overview of the State's operational efforts to contain the pandemic (speaking order)**

- Ann Hollingshead, Legislative Analyst's Office
- Teresa Calvert, Department of Finance
- Stephon Benson, Department of Finance
- Christina Curry, Chief Deputy Director, Office of Emergency Services
- Susan Fanelli, Chief Deputy Director, Department of Public Health
- Jessica Peters, Legislative Analyst's Office

Questions from Members

III. **Update on the State's procurement process and availability of personal protective equipment (speaking order)**

- Angela Shell, Deputy Director of the Procurement Division, Department of General Services
- Mitch Medigovich, Deputy Director, Office of Emergency Services
- Jessica Peters, Legislative Analyst's Office
- Department of Finance is available for Q/A

Questions from Members

IV. **Public Comment**

BACKGROUND

COVID-19 Cases in the State

According to data available as of November 4, 2020, there are a total of 940,010 of known COVID-19 cases in California and a total of 17,752 deaths. This data represents 5,338 new cases or a 0.6% increase from the prior day and 66 new deaths or a 0.4% increase from the prior day. A total of 19,181,012 total tests have been administered and the latest positivity rate (over 14 days) is 3.3%.

California's COVID-19 Vaccination Planning

California, along with Florida, Minnesota, North Dakota, and Philadelphia, is working with the Centers for Disease Control and Prevention (CDC) and the Department of Defense on a vaccine distribution plan as summarized below. The Governor's Office announced a special task force of 11 experts that will independently review all FDA approved vaccines

prior to distribution in the state. While it is possible that drug companies that have COVID-19 vaccines in trials could request emergency use authorization as soon as mid to late November, the Governor has stated that mass availability will not occur until 2021. The CDC has estimated the possibility of 35-45 million vaccine doses available nationwide by the end of 2020. The total U.S population exceeds 328 million individuals and California's population is nearly 40 million. The following information was provided on the California Department of Public Health's website and updated as of October 19, 2020:

Summary of COVID-19 Vaccination Plan submitted to the Centers for Disease Control and Prevention (CDC) on October 16, 2020

From the start of this pandemic, data and science have guided our state's response to COVID-19. That will continue to be true when it comes to a possible vaccine. While there is no proven vaccine yet, California is putting everything in place to distribute and administer vaccine doses as quickly as possible, but only after vaccine safety has been reviewed and approved by a panel of top health experts.

California's planning process for the eventual distribution and administration of COVID-19 is guided by the overarching principles of ensuring the COVID-19 vaccine meets safety requirements; ensuring that the vaccine is distributed and administered equitably, at first to those with the highest risk of becoming infected and spreading COVID-19; and transparency, by bringing in community stakeholders from the outset.

California will leverage its well-established existing immunization framework and emergency response infrastructure to coordinate efforts between state, local, and territorial authorities and administer the vaccine. The state is building on lessons learned from previous vaccination campaigns and seasonal influenza efforts to prepare and plan for the receipt and distribution of the COVID-19 vaccine and its implementation across the state.

The recruitment and enrollment of COVID-19 vaccine providers are critical processes with extensive collaboration between the state, local health departments, immunization coalitions and statewide organizations and associations. Allocation decisions will be data driven with an emphasis on equity and on protecting vulnerable populations.

California's COVID-19 vaccination plan will be implemented in several phases: Pre-vaccine; limited doses available; larger number of doses available; and sufficient supply of doses for entire population.

To accomplish the twin principles of safety and equity, California established the COVID-19 California Governor's Vaccine Task Force and a COVID-19 Vaccine Task Force Working Group with leadership and subject matter expertise. Additionally, California will draw upon the knowledge of many to ensure the following:

- To ensure the COVID-19 vaccine meets safety requirements, California will form a Scientific Safety Review Work Group comprised of nationally recognized immunization, public health, academic and other subject matter experts. The work group will be charged with staying abreast of vaccine candidate(s) trials, evidence of safety and efficacy, and other information to independently provide recommendations to California leadership and vaccine planning efforts as well as ensure public confidence in vaccine safety, efficacy, and implementation efforts.

- To ensure the vaccine is distributed and administered equitably, California will create two work groups: a Drafting Guidelines Workgroup charged with developing California-specific guidance for the prioritization and allocation of vaccine when supplies are limited, and a Community Advisory Vaccine Committee to provide input and feedback to the planning efforts and solve barriers of equitable vaccine implementation and decision-making.

A safe and effective COVID-19 vaccine is one of the most important interventions to end the COVID-19 pandemic. California will be transparent, careful, and above all, equitable in efforts to provide a COVID-19 vaccine to everyone in California who needs and requests vaccination.

Personal Protective Equipment

The COVID-19 pandemic has affected the medical product supply chain globally and domestically. The impact of COVID-19 on the availability of personal protective equipment (PPE), such as gowns, gloves, respirators, and surgical masks, for health care personnel continues to be a concern. PPE is generally worn by health care personnel to protect the wearer from infection or illness from blood, body fluids, or respiratory secretions. PPE intended for use in the cure, mitigation, treatment, or prevention of disease meet the definition of a medical device (device) under the Federal Food, Drug, and Cosmetic Act (FFDCA) and are regulated by the U.S. Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS). PPE that do not meet the FFDCA definition of device (i.e., not intended for medical use) are not regulated by FDA.

FDA Regulation of PPE

In general, any company interested in distributing medical PPE in the United States would need permission from FDA. Pursuant to its authorities in the FFDCA, FDA regulates medical devices based on the risk they pose to consumers. There are three regulatory classes of devices with different applicable requirements: class I (low risk), class II (moderate risk), and class III (high risk). Class II devices are subject to special controls, and class III devices are subject to premarket approval (PMA). However, all devices regardless of regulatory class are subject to general controls, such as establishment registration and good manufacturing practices.

Masks

Surgical Masks and Filtering Facepiece Respirators Masks are a broad category of PPE that include surgical masks and filtering facepiece respirators (FFRs). FFRs intended for medical use (e.g., surgical N95 FFRs) are subject to both National Institute for Occupational Safety and Health (NIOSH) approval and FDA regulation as devices. Surgical masks and surgical N95 FFRs are both class II medical devices that provide a physical barrier to fluids and particulate matter by covering the nose or mouth. Both are tested for fluid resistance, filtration efficiency, flammability, and biocompatibility. Surgical masks are loose-fitting, while surgical N95 FFRs form a tight seal around the nose and mouth, providing very efficient filtration (i.e., 95%) of airborne particles.

Face masks intended for nonmedical or public use generally are not subject to FDA oversight. FFRs and other respirators for occupational use (e.g., N95s for industrial use) are subject to NIOSH approval but not FDA oversight.

California secures a major supplier of PPE

On April 7, 2020, Cal OES, under emergency authority, entered into a nearly $1 billion purchase agreement with BYD, a Chinese manufacturer, for 200 million surgical and N95 respirator masks per month amid the pandemic. Details of the agreement were publicly released on May 6, 2020.

Previous oversight hearing focused on initial efforts to procure PPE

On May 11, 2020, the Assembly Committee on Accountability and Administrative Review held an oversight hearing on state contracting during emergencies. Among other things, the hearing focused on the state's procurement of PPE such as gloves, masks, gowns and face shields for medical and other essential workers. The Committee heard testimony from Cal OES and DOF regarding the Administration's use of emergency authority to enter into the contract with BYD and lessons learned from reported instances of PPE contracts being cancelled by the State due to fraud and other misrepresentations. As a result of these concerns, Cal OES adopted a more robust vetting process of PPE vendors which includes input from federal emergency management and law enforcement officials.

Stockpiling PPE in advance of an expected surge of demand this Fall

On July, 22, 2020 the Governor announced that the Governor's Office of Emergency Services entered into a new contract with California-based BYD North America to produce 120 million N-95 respirators and 300 million surgical masks for the state. At the time, the Governor noted, "Providing front-line workers the protective equipment they need is critical to our state's response to COVID-19. Securing a reliable supply chain of PPE allows us to distribute millions of protective masks to our essential workforce while preserving millions more in our state's stockpile for future use."

Additional mandate for stockpiling PPE

On September 29, 2020, the Governor signed SB 275 (Pan), which requires the California Department of Public Health (CDPH) to establish a personal protective equipment (PPE) stockpile for health care workers and essential workers in the state and requires health care employers to establish a PPE inventory that is sufficient for at least 45 days of surge consumption.

Considerations for the Legislature

Availability of and access to PPE has been a concern throughout the COVID-19 pandemic. PPE shortages have presented challenges for both health care personnel treating patients in medical settings and expansion of COVID-19 testing. The challenges will be amplified as we enter the colder months, with more people congregating inside and becoming ill with the cold or flu. Additionally, the State can anticipate similar challenges if a COVID-19 vaccine becomes available in the near future.

Based on prior oversight hearings, the extent to which vendors and brokers are vetted remains a challenge and there is limited information available on instances of vendors or brokers that have been rejected by a vetting process or reported to be bad actors.

With respect to the distribution and allocation of PPE, Cal OES has indicated that there is a process in place to determine how limited quantities of PPE is distributed if demand for a particular resource exceeds current inventory. The Legislature may benefit from more transparency on the process and the factors that determine the allocation of scarce resources.