

Date of Hearing: April 5, 2021

ASSEMBLY COMMITTEE ON EMERGENCY MANAGEMENT

Freddie Rodriguez, Chair

AB 805 (Maienschein) – As Introduced February 16, 2021

**SUBJECT:** Personal protective equipment: distribution reports

**SUMMARY:** Requires medical health operational area coordinators (MHOAC) to report information relating to the distribution of personal protective equipment (PPE) to the California Office of Emergency Services (Cal OES) on a weekly basis during declared emergencies, and monthly at all other times. Specifically, **this bill:**

- 1) Requires MHOAC's to include in their medical and health disaster plan, reporting obligations on PPE distribution to Cal OES.
- 2) During a proclaimed health-related state of emergency, the MHOAC shall report to Cal OES on a weekly basis. At all other times, the MHOAC will report monthly. The information to be reported includes the locations, names, and addresses of each facility to which PPE has been distributed, including each type of PPE distributed and its allocated amount.
- 3) During health-related state of emergencies, Cal OES shall post and update the information provided by MHOAC's regarding PPE to its website on a weekly basis, and monthly at all other times.
- 4) Defines PPE to mean all the following:
  - a) N95 filtering facepiece respirators;
  - b) Powered air-purifying respirators with high-efficiency particulate air filters;
  - c) Elastomeric air-purifying respirators with appropriate particulate filters or cartridges;
  - d) Surgical masks;
  - e) Isolation gowns;
  - f) Eye protection;
  - g) Shoe coverings; and
  - h) Gloves.

**EXISTING LAW:**

- 1) Authorizes the county health officer and the local Emergency Medical Services (EMS) agency administrator in an operational area to act jointly as a MHOAC, or appoint another entity to the role, to fulfill the responsibilities of cooperating with local and state agencies in the development of a medical and health disaster plan for purposes of mutual aid within that operational area.
- 2) Requires that a MHOAC shall recommend a medical and health disaster plan to the operational area coordinator within Cal OES.
- 3) Requires that a medical and health disaster plan include preparedness, response, recovery, and mitigation functions consistent with the State Emergency Plan, including an assessment of immediate medical needs, the coordination of medical and health resources, the coordination between local and state agencies, and other emergency care providers, the

assurance of safe drinking water, and the investigation and control of communicable disease, among other things.

- 4) In the event of a local, state, or federal declaration of emergency, requires MHOACs to assist the operational area coordinator in coordinating medical and health disaster resources in the operational area, and be the point of contact for coordination between local EMS agencies, Cal OES, the California Department of Public Health (CDPH), and the Emergency Medical Services Authority (EMSA).

**FISCAL EFFECT:** Unknown.

**COMMENTS:**

Purpose of the bill: According to the author, "PPE is one of the most important tools we have in the fight against COVID-19. Adequate PPE for our frontline healthcare workers is an important part of infection control policy and not only protects workers and patients, but the general public from greater spread of the virus."

The author adds, "even though MHOACs are a local government entity, it has been difficult for policymakers and stakeholders to receive timely information on PPE procurement. This bill is an important measure that provides transparency and timely information to help the state, policymakers, stakeholders and the public respond during a crisis."

Background: At the state level, medical and health response planning is accomplished by several departments under the California Health and Human Services Agency (CHHSA) in coordination with plans prepared by Cal OES. For purposes of mutual aid, Cal OES divides operational areas into six regions. For each region, EMSA and CDPH jointly appoint a regional disaster medical and health coordinator (RDMHC), whose responsibilities include supporting the mutual aid requests of a MHOAC, in addition to serving as an information source to the state medical and health response system. According to EMSA, there are currently 83 MHOACs in the State that fall under the six mutual aid regions. If a RDHMC is unable to fulfill a request by a MHOAC due to limited resources within the mutual aid region, the RDHMC will forward to the request to one of three CalOES Regional Emergency Operation Centers (Costal, Inland, Southern) or to the State Operations Center to fill the request.

Personal Protective Equipment (PPE): 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 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 FDCA, 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 secured 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.

Stockpiling PPE in advance of last year's surge in demand: 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 mandates for stockpiling PPE: Last year, the Governor signed AB 2537 (Rodriguez), which requires employers who employ workers who provide direct patient care in the hospital setting to maintain a stockpile of unexpired PPE in the amount equal to six months of normal consumption and SB 275 (Pan), which requires the 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.

Arguments in support: The California Nurses Association/ National Nurses United (CNA), write in support, "this bill will create transparency around personal protective equipment (PPE) procurement and distribution at the local level by ensuring the Medical Health Operational Area Coordinator (MHOAC) reports PPE distribution information regularly to the California Office of Emergency Services (OES)."

The California Labor Federation adds, “this bill is good common sense public health, worker safety, and public disclosure policy. Government is supposed to be accountable and transparent to the public.”

Prior legislation: AB 2537 (Rodriguez), Chapter 313, Statutes of 2020. Requires employers who employ workers who provide direct patient care in the hospital setting to maintain a stockpile of unexpired PPE in the amount equal to six months of normal consumption. SB 275 (Pan), Chapter 301, Statutes of 2020. Requires CDPH to establish a PPE stockpile to ensure an adequate supply of PPE for all health care workers and essential workers in the state that is sufficient for a 90-day pandemic or other health emergencies.

**REGISTERED SUPPORT / OPPOSITION:**

**Support**

California Labor Federation  
California Nurses Association/ National Nurses United (CNA)

**Opposition**

None on file.

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