FINDING OF EMERGENCY

DEPARTMENT OF INDUSTRIAL RELATIONS DIVISION OF OCCUPATIONAL SAFETY AND HEALTH PROPOSED EMERGENCY STANDARD, TITLE 8, CALIFORNIA CODE OF REGULATIONS REGULATIONS OF THE DIVISION OF OCCUPATIONAL SAFETY AND HEALTH CHAPTER 3.2, SUBCHAPTER 2, ARTICLE 1.7, SECTION 340.7

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Government Code section 11346.1, subdivision (a)(2) requires that, at least five working days prior to submission of the proposed emergency action to the Office of Administrative Law, the adopting agency provide a notice of the proposed emergency action to every person who has filed a request for notice of regulatory action with the agency. After submission of the proposed emergency to the Office of Administrative Law, the Office of Administrative Law shall allow interested persons five calendar days to submit comments on the proposed emergency regulations as set forth in Government Code section 11349.6.

The Chief of the Division of Occupational Safety and Health (the Division) hereby finds that an emergency exists and that the proposed regulations are necessary to avoid serious harm to the public peace, health and safety, or general welfare, pursuant to Government Code section 11342.545.

FINDING OF EMERGENCY

Specific Facts Demonstrating the Need for Immediate Action

1. AB 2537 (Rodriguez) was introduced in 2020 with the following comment:

The nationwide supply shortage of personal protective equipment during this global pandemic is well-documented. Due to this shortage, frontline healthcare workers have reported being required to preserve PPE [personal protective equipment] by re-using PPE. According the California Department of Public Health, as of August 26, 2020, local health departments have reported 31,115 confirmed positive cases of COVID-19 in health care workers and 150 deaths statewide. This bill seeks to protect healthcare workers from further spread of COVID-19 as well as ensure adequate supply of PPE to prepare for the future.

- 2. On September 29, 2020, Governor Newsom signed AB 2537 into law, which adopted Labor Code section 6403.3. Among other things, section 6403.3 requires that an employer, as defined, establish and implement procedures for determining the quantity and types of equipment used in its "normal consumption" (Lab. Code § 6403.3, subd. (f)) and, beginning April 1, 2021, maintain a stockpile of specified equipment in the amount equal to "three months of normal consumption" (Lab. Code § 6403.3, subd. (c)(1)). The law does not define the phrase "normal consumption," nor is it defined elsewhere in the Labor Code or Title 8 of the California Code of Regulations. Additionally, this new law does not define how the time period of three months should be calculated.
- 3. Under the new law, an employer means a person or organization that employs workers in the public or private sector to provide direct patient care in a general acute care hospital, as defined. The equipment to be stockpiled generally includes N95 filtering facepiece respirators, powered air-purifying respirators, elastomeric air-purifying respirators, surgical masks, isolation gowns, eye protection, and shoe coverings.
- 4. The Division is authorized under Labor Code section 6403.3, subdivision (g) to enforce an alleged violation of the statute through the issuance of a citation with penalties up to \$25,000. (See Lab. Code, 6317.)
- 5. Since shortly after AB 2537 was signed into law, impacted employers have had questions about the meaning of the normal consumption requirement. For example, does "normal consumption" mean: (1) a static amount, based on one snapshot in time; or (2) an amount of time that takes into account fluctuations of usage and demand that should be regularly re-calculated. Further, many, if not most, impacted employers have indicated they do not track daily equipment consumption rates as a matter of course; thus, they are uncertain as to what

procedures would constitute acceptable methods of calculation. Additionally, the statute is open to interpretation as to what method or methods impacted employers may use to determine consumption rates.

- 6. Given the need for regulatory interpretation of Labor Code section 6403.3 to clarify the meaning of "normal consumption" and how to calculate "three months of normal consumption," employers lack clear direction as to how to comply while the Division is substantially hampered, if not precluded from consistently and uniformly enforcing the requirements of the statute. This dilemma is compounded by the effective date of the statute, which is April 1, 2021.
- 7. During the Covid-19 pandemic, hospitals reported that widespread shortages of personal protective equipment (PPE) put staff and patients at risk. Hospitals reported that heavier use of PPE than normal was contributing to the shortage and that the lack of a robust supply chain was delaying or preventing them from restocking PPE needed to protect staff. Hospitals also expressed uncertainty about the availability of PPE from federal and state sources and noted some vendors had sharply increased the prices of PPE.¹
- 8. As a consequence of PPE shortages, workers who provide direct patient care or provide services that directly support patient care ("hospital workers") have experienced workplace practices that have threatened their health and safety. To try to make existing supplies of PPE last, hospitals reported conserving and reusing single-use/disposable PPE, including using or exploring ultra-violet (UV) sterilization of masks or bypassing some sanitation processes by having staff place surgical masks over N95 masks. Hospitals also reported turning to non-medical-grade PPE, such as construction masks or handmade masks and gowns, which they worried may put staff at risk.² As of March 9, 2021, the California Department of Public Health has reported 97,997 confirmed positive cases in health care workers and 409 deaths statewide.³
- 9. Hospitalizations as a result of Covid-19 are ongoing and, despite the increase in the number of vaccinations, variants of the virus continue to raise serious public health and safety concerns. Thus, without immediate regulatory action, the public health and safety, or general welfare may be negatively impacted because of insufficient supplies of PPE for hospital workers. The adoption of the proposed regulations would avoid such harm by making the stockpile requirement of Labor Code section 6403.3 clear, specific, and enforceable.

AUTHORITY AND REFERENCE CITATIONS

Labor Code section 60.5, subdivision (b) provides that the Division of Occupational Safety and Health succeeds to and is vested with all of the powers, duties, purposes, responsibility, and jurisdiction of the Division of Industrial Safety.

Labor Code section 6308, provides that in enforcing occupational safety and health standards and orders and special orders, the Division may:

¹ US Department of Health and Human Services. Office of the Inspector General. Hospital Experiences Responding to the COVID-19 Pandemic: Results of a National Pulse Survey March 24-27, 2020. <u>Hospital Experiences Responding to the COVID-19 Pandemic: Results of a National Pulse Survey March 24-27, 2020 (OEI-06-20-00300; 04/20) (hhs.gov)</u>

² US Department of Health and Human Services. Office of the Inspector General. Hospital Experiences Responding to the COVID-19 Pandemic: Results of a National Pulse Survey March 24-27, 2020. <u>Hospital Experiences Responding to the COVID-19 Pandemic: Results of a National Pulse Survey March 24-27, 2020 (OEI-06-20-00300; 04/20) (hhs.gov)</u>

³ California Department of Public Health, "State Officials Announce Latest COVID-19 Facts," accessed August 9, 2020, <u>State Officials Announce Latest COVID-19 Facts</u>

(a) [d]eclare and prescribe what safety devices, safeguards, or other means or methods of protection are well adapted to render the employees of every employment and place of employment safe as required by law or lawful order.

[**¶**]...[**¶**]

(c) Require the performance of any other act which the protection of the life and safety of the employees in employments and places of employment reasonably demands.

Authority Cited: Sections 60.5 and 6308, Labor Code.

Reference: Section 6403.3, Labor Code.

INFORMATIVE DIGEST OF PROPOSED ACTION

Summary of Existing Regulations and the Effect of the Proposed Regulation

Existing law requires an employer to furnish employment and a place of employment that is safe and healthful for its employees and to establish, implement, and maintain an effective Injury and Illness Prevention Program (IIPP), as prescribed. Regulations enacted by the Occupational Safety and Health Standards Board (OSHSB) regulate the nature and use of PPE and regulate practices in health care facilities connected with aerosol transmissible diseases.

Existing standards in Title 8 of the California Code of Regulations (8 CCR), including 8 CCR § 3380⁴ and 8 CCR § 5199,⁵ require employers to furnish PPE to their employees and to require its use.

Employers subject to the Aerosol Transmissible Diseases (ATD) standard (including public and private hospitals) must make provisions for the stockpiling of required PPE (called "surge procedures") in their ATD plans⁶ (8 CCR § 5199(d)(2)(Q)). This section does not specify the amount of PPE that employers are required to stockpile for a surge, only that they establish procedures for doing so.

New Labor Code section 6403.3(c)(1) requires that beginning April 1, 2021, general acute care hospitals maintain an un-expired and unused stockpile of specified respirators, particulate filters or cartridges, surgical masks, isolation gowns, eye protection, and shoe coverings, in an amount equal to three months of "normal consumption."

"Normal consumption" is not defined in the new law and thus regulatory action is needed to interpret the phrase so that it is sufficiently clear and specific to allow impacted employers to properly comply with the statute's requirements. Such regulatory action is also needed so that the Division can consistently and uniformly enforce those requirements.

The proposed emergency regulation would define "normal consumption," including a statutory formula for calculating "three months of normal consumption" and acceptable methods of calculation.

⁴ §3380. Personal Protective Devices.

⁵ §5199. Aerosol Transmissible Diseases.

⁶ Section 5199(d) requires employers to establish, implement, and maintain an effective ATD Exposure Control Plan that contains all of the elements set forth in Section 5199(d)(2), including surge provisions.

This proposed emergency standard would be in Subchapter 2, Regulations of the Division of Occupational Safety and Health.

[Proposed] Article 1.7 Definitions

[Proposed] Section 340.7 Definition of "Normal Consumption"

The proposed emergency regulation would specify that, for purposes of the regulation, "employees" means those who provide direct patient care or who provide services that directly support patient care in a general acute care hospital and "facility" means a "general acute care hospital."

This provision is necessary for purposes of clarity, to enable affected employers to comply with the subsequent sections of the regulation that use those terms, and to ensure consistency with the provisions of Labor Code section 6403.3.

The proposed emergency regulation would define normal consumption as the average amount of the equipment specified, for each category, type, and size of equipment, used by all employees over the previous two-year period. The equipment specified would include N95 filtering facepiece respirators, powered airpurifying respirators with high efficiency particulate air filters, elastomeric air-purifying respirators and appropriate particulate filters or cartridges, surgical masks, isolation gowns, eye protection, and shoe coverings.

This provision is necessary to establish that "normal consumption" is a projected level of demand based on an average of past consumption levels. It includes consumption by both employees who provide direct patient care and who provide services that support patient care. It also accounts not just for each category of specified equipment, which are individually set forth to provide clarity to affected employers, but the underlying types and sizes of each category used by employees as well.

This provision is necessary to establish that "normal consumption" is not a static amount based on one snapshot in time, but rather a two-year average that reflects the natural variations in consumption levels that occur over time based on fluctuations in demand. Including this variability is critical to obtaining a calculated average that is a reasonable representation of the amount of specified equipment actually used by hospital workers. This will reduce the likelihood that an employer will inadvertently underestimate the amount of equipment needed, thereby defeating the statutory purpose of maintaining a stockpile of specified equipment in order to avoid shortages.

This provision is also necessary to establish a reasonable sample period for determining the normal consumption of the equipment specified. If the sample period is too short, fluctuations in usage, which naturally occur over time depending upon need and circumstances, may create an average that is artificially high or artificially low. If the sample period is too long, data collection and retention may be impractical or overly burdensome. The two-year "look back" period is intended to strike a balance between these considerations.

The proposed emergency regulation would delineate how normal consumption is calculated. For each year beginning April 1, the quantity of each category, type, and size of the specified equipment consumed by employees in the facility during the preceding two calendar years, from January through December, shall be added up and then divided by 8.

This provision is necessary to establish a uniform and straightforward formula that employers can use to calculate the required size of the stockpile and, for enforcement purposes, the Division can apply to determine whether an employer's stockpile is in compliance. Because section 6403.3, subdivision (c)(1) requires a stockpile in an amount equal to three months of normal consumption, the quantity of specified equipment consumed in the facility during each twenty-four-month period (January through December) is divided by 8. The calculation for each year, beginning April 1, is based on the preceding two-year period from January through December. This provides a three-month window, from January through March, for an employer to calculate normal consumption and adjust its stockpile accordingly.

The proposed emergency regulation would specify that in calculating the normal consumption over the specified two year timeframe the quantity used to represent consumption during the *second year* shall be capped at 200% of the *first year* consumption total. The second year's capped quantity, rather than its actual quantity, shall be used as that year's consumption total for calculations in subsequent years.

This provision is necessary to account for consumption levels that may be unusually extreme or high and thus unreasonably skew the average two-year demand for equipment. The intent of the cap is to strike a balance between the need to prevent extreme deviations in usage from excessively distorting the average use or demand and the need to account for the fact that, to some extent, such deviations should not be dismissed entirely since an inherent uncertainty of actual demand does exist.

The proposed emergency regulation would contain a note that provides the following example of how the cap works when calculating three months of normal consumption for a particular type of equipment: Three months of normal consumption for the year beginning April 1, 2021, and ending on March 31, 2022, would be based on the total quantity of each category, type, and size of the specified equipment consumed during the period January 1, 2019, through December 31, 2020, divided by 8. Assume that consumption of a particular category and type of equipment, in a size medium, was 1000 pieces in 2019, 3000 pieces in 2020, and 1600 pieces in 2021. The quantity used to calculate the normal consumption for 2020 will be capped at 2000 pieces (1000 x 2). The calculation for three months of normal consumption for the year starting April 1, 2021, will thus be (1000 plus 2000)/8 = 375 pieces. The calculation for three months of normal consumption for the year starting April 1, 2022, will be (2000 plus 1600)/8 or 450 pieces.

This provision is necessary to provide clarity as to how to calculate three months of normal consumption using the cap and to illustrate precisely how the cap is applied in the following two-year period.

The proposed emergency regulation would set forth four different methods by which an employer may determine consumption for each category, type, and size of equipment. These would include the total quantity received in the facility from all sources for use by employees; the total quantity ordered by the facility from all sources for use by employees; the average monthly inventory, or; the quantity distributed to units in which employees provide patient care and to units providing services that directly support patient care, through all distribution methods, including separately chargeable and non-separately chargeable items.

This provision is necessary to provide clarity and specificity as to the types of data that an employer may use to calculate its consumption rates. Many, if not most, affected employers do not maintain records of daily consumption levels for each category, type, and size of the specified equipment used by hospital workers. The options set forth in this section represent different proxies that employers may use in lieu of such data. Each of the four methods utilize types of data that different hospitals already collect in the normal course of business, allowing hospitals to easily apply pre-existing data in this context, rather than requiring the creation of new internal data collection systems.

The proposed emergency regulation would also contain a note that states that an employer may use different methods of determining consumption, from among the four methods listed in the regulation, for each category and type of equipment.

This provision is necessary to address circumstances where an employer does not track each category and type of equipment in the same manner. It allows the employer the flexibility to choose which method to use for each category, so that pre-existing data can be used and new data collection systems are not required.

Policy Statement and Anticipated Benefits

The objective of this proposed regulatory action is to implement, interpret, and make specific the policy set forth in Labor Code section 6403.3. Specifically, the Division is proposing this emergency regulation to clarify the meaning of "normal consumption" and to provide a straightforward and understandable formula for calculating three months of "normal consumption." The proposed regulation is being implemented on an emergency basis, rather than through the regular rulemaking process, for the immediate preservation of the public peace, health and safety, or general welfare, within the meaning of Government Code section 11346.1.

The anticipated benefits of this proposed regulation are many. The regulation will provide employers with clear direction as to what their obligations are under the stockpile requirement of the new law, so that they can in turn satisfy that requirement. As of April 1, 2021 and beyond, employers will not be left to speculate or guess whether or not the stockpile amount they have set aside will be deemed sufficient or insufficient and thus subject to citation and related penalties.

Additionally, the proposed regulation will enable the Division to consistently and uniformly enforce the stockpile requirement. This will result in heightened occupational safety and health for impacted hospital workers.

Further, the definition of "normal consumption" will yield realistic average demand levels for employers to use when calculating stockpile amounts, thereby minimizing the risk that employers will underestimate the amount of protective equipment that must be maintained. As such, the proposed regulation will help ensure that healthcare workers have sufficient levels of protective equipment, particularly during periods of heightened demand, to safely perform their work, thus minimizing exposures and the potential for illness, even serious illness.

The proposed regulation will also help avoid disruptions to patient care caused by the need to preserve equipment or by the absence of healthcare workers due to illness. Additionally, minimizing exposures and resulting illnesses of healthcare workers will help reduce transmission of Covid-19 in the workplace, including transmissions between healthcare workers and patients and between healthcare workers and their families, friends, and members of the public. Thus, this proposed regulation, by promoting the health and safety of healthcare workers, will mean more effective containment of Covid-19 for the public at large.

The proposed emergency regulation would likely have economic benefits as well. Maintaining a sufficient stockpile of PPE for healthcare workers would allow the workforce to remain in place, even during periods of heightened demand, thus decreasing potential costs from unemployment. The regulation would also prevent the unnecessary expense of purchasing PPE at rates that are often inflated during periods of heightened demand.

Federal Regulations and Statutes

No federal law or regulation exists or has been promulgated that specifically defines "normal consumption."

Evaluation of Inconsistency/Incompatibility with Existing State Regulations.

A review of regulations adopted by this and other comparable agencies has been conducted and the Division has determined that the proposed emergency regulation is not inconsistent or incompatible with any existing state regulations.

DOCUMENTS INCORPORATED BY REFERENCE

None.

TECHNICAL OR THEORETICAL, OR EMPIRICAL STUDIES, REPORTS, OR DOCUMENTS RELIED ON

The Division has relied upon the following documents as part of this emergency action:

- US Department of Health and Human Services. Office of the Inspector General. Hospital Experiences
 Responding to the COVID-19 Pandemic: Results of a National Pulse Survey March 24-27, 2020. Hospital
 Experiences Responding to the COVID-19 Pandemic: Results of a National Pulse Survey March 24-27,
 2020 (OEI-06-20-00300; 04/20) (hhs.gov)
- 2. California Department of Public Health, "State Officials Announce Latest COVID-19 Facts," accessed August 9, 2020, https://www.cdph.ca.gov/Programs/OPA/Pages/NR21-081.aspx

MANDATE ON LOCAL AGENCIES OR SCHOOL DISTRICTS

The Division has determined that proposed section 340.7 does not impose a mandate on local agencies or school districts requiring reimbursement by the State pursuant to Part 7 of Division 4 of the Government Code (commencing with section 17500).

FISCAL IMPACT OF PROPOSED ACTION

Costs or Savings to State Agencies:

There are five state hospitals in California. These hospitals are not general acute care hospitals and thus are not subject to the requirements of Labor Code section 6403.3. They would not incur any costs or savings as a result of the proposed emergency regulation.

Cal/OSHA will already be required to enforce Labor Code section 6403.3, and incur any costs associated therewith, and would not incur any additional costs as a result of this proposed emergency regulation.

Cost to Any Local Agency or School District Which Must Be Reimbursed in Accordance With Government Code Sections 17500 through 17630: None.

Other Nondiscretionary Cost or Savings Imposed on Local Agencies:

There are 21 public health care systems in California. The general acute care hospitals in these systems are subject to the requirements of Labor Code section 6403.3 and may be impacted by the proposed regulation.

The potential fiscal impact that the definition of "normal consumption" in this proposed emergency regulation may have on these entities cannot be quantified at this time because there is currently no standard definition of "normal consumption." Because no baseline case exists, the proposed regulatory definition may result in savings or costs, depending on how the employer currently interprets the phrase.

As of April 1, 2021, Labor Code section 6403.3(c)(1) requires each hospital to maintain a stockpile of seven specified types of equipment equal to three months of normal consumption. If they do not have existing stockpiles of this volume, hospitals will incur costs to come into compliance with the statute. Such costs will be incurred under the statutory stockpile requirement of Labor Code section 6403.3, regardless of this emergency rulemaking action.

The only potential economic impact this rulemaking would have would be the difference between the costs of a hospital's pre-existing statutorily required stockpile, created in the absence of a definition of "normal consumption," and the costs of a stockpile amassed using the proposed regulatory definition of "normal consumption," to the extent those amounts may differ. Such costs may include not only the cost of additional equipment needed to bring a stockpile inventory into compliance, but also costs related to additional space needed to store such equipment, depending on the employer's degree of non-compliance.

The potential economic impact of the proposed regulatory definition is shown in the calculations below. For this analysis, Cal/OSHA posits three hypothetical scenarios involving N95 filtering facepiece respirators (N95s): one in which a hospital uses pre-March 2020 consumption data, another in which a hospital uses post-March 2020 consumption data, and a third in which a hospital uses the proposed regulatory definition of normal consumption.

Hypothetical Annual Consumption of N95sat 350-Bed Hospital 7

Pre-March 2020 Annual Consumption (Based on January 2020 Consumption)	Post-March 2020 Annual Consumption (Based on Nov. 2020 Consumption)
145,200	286,428

Hypothetical Three-Month Stockpile Cost of N95s

	Three-Month Stockpile Size	Total Cost of N95s (Unit Cost x # of Units)	Total Cost of Storage (Annual Cost Per Square I Square Footage)
Scenario 1: Stockpile Based on Pre-March 2020 Consumption Only	36,300	\$39, 930.00	\$729.60-\$2227.20

⁷ Data provided by California Department of Public Health.

	Three-Month Stockpile Size	Total Cost of N95s (Unit Cost x # of Units)	Total Cost of Storage (Annual Cost Per Square I Square Footage)
Scenario 2: Stockpile Based on Post-March 2020 Consumption Only	71,607	\$78,767.70	\$1459.20 - \$4454.40
Scenario 3: Stockpile Based on Proposed Regulatory Definition	53,954	\$59,349.00	\$1,094.40 - \$3,340.80

The cost per unit for N95s is approximately \$1.10.8

The space required to store 200 boxes of N95s, with 50 N95s per box, is approximately 16 square feet. Under Scenario 1, 36,300 N95s would require approximately 4 pallets, or 64 square feet of storage space. Under Scenario 2, 71,607 N95s would require approximately 8 pallets, or 128 square feet of storage space. Under Scenario 3, 53,954 N95s would require approximately 6 pallets, or 96 square feet of storage space.

Based on data obtained for four different locations in the California, the cost of storage is between approximately \$11.40 and \$34.80 per square foot, for a yearlong storage locker rental.¹¹

As shown above, relative to Scenario 1, the proposed regulatory definition would result in a cost increase. However, relative to Scenario 2, the proposed regulatory definition would result in a cost savings. Potential costs or savings created by this proposed emergency regulation cannot be quantified because each employer's degree of non-compliance with the stockpile amount required using the proposed regulatory definition of "normal consumption" cannot be ascertained at this time.¹²

Costs or Savings In Federal Funding To The State: None.

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⁸ Data provided by the Division of Occupational Safety and Health's Calibration and Inventory Control (CALICO) Laboratory for the cost of 3M N95s purchased in bulk.

⁹ Based on data provided by CALICO Laboratory, 200 boxes occupy approximately one pallet, measuring 4 feet x 4 feet. ¹⁰ Based on data provided by CALICO Laboratory, the height of 200 boxes stacked on a 4 foot x 4 foot is approximately 4 feet. According to storage.com, the average height of a storage unit is approximately 8 feet. Certain storage units may thus have sufficient space to stack the pallets, thereby decreasing the total square footage required. For the purposes of the calculations herein, however, because the feasibility of stacking is unknown, square footage is calculated based on the space required for unstacked pallets.

¹¹ Data obtained from sparefoot.com indicates that the approximate cost of a 100 square foot storage locker is \$3480 per year in San Francisco (\$34.80 per square foot), \$2232 per year in Sacramento (\$22.20 per square foot), \$2112 in San Bernardino (\$21.12 per square foot), and \$1140 in Redding (\$11.4 per square foot).

¹² During the time that this emergency regulation is in effect and the Division is working to adopt a permanent regulation, the Division will gather data from affected employers to determine the quantity of each category, type and size of the specified equipment that was maintained in the employer's pre-existing statutory stockpile. This data will enable the Division to determine the difference, if any, between that amount and the amount maintained once "normal consumption" was defined, and the costs or savings associated therewith.

(Title 1 CCR section 50(a)(5)(A))

The Division has complied with the provisions of Government Code section 11346.1(a)(2), regarding the sending of notice of proposed emergency regulations action to every person who has filed a request for notice of regulatory action. The notice was sent electronically on June 8, 2021, to members and attendees of the Cal/OSHA Advisory Committee, at least five working days prior to submission to the Office of Administrative Law on June 15, 2021.