

**STATE OF CALIFORNIA
DEPARTMENT OF INDUSTRIAL RELATIONS
DIVISION OF OCCUPATIONAL SAFETY AND HEALTH**

INITIAL STATEMENT OF REASONS

CALIFORNIA CODE OF REGULATIONS

TITLE 8: New Section 340.70 of the Regulations of the Division of Occupational Safety and Health

Definition of Normal Consumption

SPECIFIC PURPOSE AND FACTUAL BASIS OF PROPOSED ACTION

The objective of this proposed regulation is to implement, interpret, and make specific the policy set forth in Labor Code section 6403.3. Specifically, the Division is proposing this regulation to clarify the meaning of “normal consumption” and to provide a straightforward and understandable formula for calculating three months of “normal consumption.”

Labor Code section 6403.3(c)(1) requires that 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 statute 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.

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

As a consequence of PPE shortages, workers who provide direct patient care or provide services that directly support patient care experienced workplace practices that threatened their health and safety. To try to make existing supplies of PPE last, hospitals reported conserving and reusing single-use/disposable PPE, bypassing some PPE sanitation processes, and/or turning to non-

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. 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)

medical-grade PPE, which they worried may put staff at risk.² As of February 24, 2022, the California Department of Public Health has reported 148,051 confirmed positive cases in health care workers and 568 deaths statewide.³

Hospitalizations as a result of Covid-19 are ongoing and, despite widespread use of vaccinations, variants of the virus continue to raise serious public health and safety concerns. The Delta variant created a new surge that began in July 2021 and led to over a 700% increase in hospitalizations in California over a two month time period.⁴ Omicron, a subsequent variant, led to a new surge that began in December 2021. With each new surge comes upticks in hospitalizations requiring heightened levels of PPE. Furthermore, future surge events caused by illness or other health emergencies which, like Covid-19, would require adequate amounts of specified protective equipment to protect health care workers, are inevitable.

Without regulatory action, worker health may be impacted because of insufficient supplies of PPE for hospital workers. The proposed regulation will help avoid such harm by making the stockpile requirement of Labor Code section 6403.3(c) clear, specific and enforceable. This will help ensure that hospital 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.

New Section 340.70. Definition of Normal Consumption

This proposed standard, new section 340.70, would be in Subchapter 2, Regulations of the Division of Occupational Safety and Health. It would be under new Article 1.7 Definitions. The regulation would include the following provisions.

New Section 340.70(a)

Proposed subsection (a) specifies 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.

New Section 340.70(b)

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. 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)

³ California Department of Public Health, “State Officials Announce Latest COVID-19 Facts,” accessed February 25, 2022, <https://www.cdph.ca.gov/Programs/OPA/Pages/NR22-037.aspx>

⁴ California Department of Public Health, “State Public Health Officer Order of August 16, 2021,” <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Order-of-the-State-Public-Health-Officer-Hospital-and-Health-Care-System-Surge.aspx>

Proposed subsection (b) defines 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 includes N95 filtering facepiece respirators, powered air-purifying 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.

New Section 340.70(c)

Proposed subsection (c) delineates how normal consumption is calculated. Subsection (c)(1) sets forth that 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. .

Subsection (c)(2) specifies 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.

Subsection (c) contains 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 $(1000 \text{ plus } 2000)/8 = 375$ pieces. The calculation for three months of normal consumption for the year starting April 1, 2022, will be $(2000 \text{ plus } 1600)/8$ 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.

New Section 340.70(d)

Proposed subsection (d) sets forth four different methods by which an employer may determine consumption for each category, type, and size of equipment. These 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.

Proposed subsection (d) also contains 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.

ANTICIPATED BENEFITS OF THE PROPOSED RULEMAKING

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 Labor Code 6403.3, so that they can in turn satisfy that requirement. 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 illness 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 illness, including C for the public at large.

The proposed 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.

SPECIFIC TECHNOLOGY OR EQUIPMENT

This proposal will not mandate the use of specific technologies or equipment. The specified equipment referenced in the proposed regulatory definition is mandated by Labor Code 6403.3(c).

**ECONOMIC IMPACT ASSESSMENT PER GOVERNMENT CODE SECTION
11346.3(b)**

There are approximately four hundred and fifteen (415) general acute care hospitals in California, including approximately three hundred and sixty (360) private hospitals, 54 local hospitals and 1 state hospital.

As of April 1, 2021, Labor Code section 6403.3(c)(1) required each such hospital to maintain a stockpile of seven specified types of equipment in an amount equal to three months of “normal consumption.” If they did not have existing stockpiles of this volume, the hospitals incurred costs to come into compliance with the statute. Such costs were incurred under the statutory stockpile requirement.

The only potential economic impact this regulation 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.

Calculation of Additional Equipment Units Needed Under Regulatory Definition:

In order to calculate the foregoing, with the assistance of the California Hospital Association, the Division issued an anonymous survey to general acute care hospitals, requesting 2019 and 2020 consumption totals pertaining to the seven specified categories of equipment required to be stockpiled under the statute, as well as existing stockpile inventory amounts. Complete data was received from a sample of 55 general acute care hospitals.

Using the 2019 and 2020 consumption totals provided, the Division calculated the stockpile size that each respondent would be required to maintain, for each category of specified equipment, under the regulatory definition of normal consumption. The Division then compared that amount to the amount of each category of specified equipment that each respondent had actually stockpiled in the absence of a regulatory definition, to determine the total additional amount of each specified category of equipment that would be needed to bring the stockpile amounts into compliance.

The totals, in each category of specified equipment, were extrapolated to a sample size of 360 hospitals, to determine the total amount of additional equipment that would be required by the state’s private general acute care hospital population.

Additional Units of Specified Equipment Required (Total for 360 Private General Acute Care Hospitals)

N95s	PAPRs	Elastomeric	Surgical Masks	Isolation Gowns	Eye Protection	Shoe Covers
89,817	1,080	373	1,177,344	1,698,683	14,099	552,122

The equipment shortfalls calculated using the existing sample of 55 hospitals were not evenly distributed among hospitals of different capacities. The Division therefore also calculated the average additional amount of each category of specified equipment that a hospital in each of the 8 capacity ranges identified on the survey⁵ would be required to amass.

Average Additional Units of Specified Equipment Required Per Hospital (By Hospital Capacity)

Hospital Bed Count	N95s	PAPRs	Elastomeric	Surgical Masks	Gowns	Eye Protection	Shoe Covers
0-50	0	0	0	0	0	0	225
51-150	3	2	0	992	2,111	0	355
151-200	0	5	0	0	4,665	0	3,707
201-300	0	2	0	0	0	0	1,010
301-400	625	1	0	4,454	2,911	77	1,936
401-500	1,184	1	11	7,099	31,843	99	2,758
501-600	1,223	48	0	50,650	6,813	408	4,050
600+	159	0	0	0	2,941	51	2,763

Calculation of Equipment Costs:

The Division conducted market research into the cost of the seven (7) categories of specified equipment required to be maintained in each stockpile.⁶

The quantities of each type and size of specified equipment category consumed at each affected hospital is unknown. To determine cost per each category of equipment, Division staff selected a sample of a minimum of two types of each equipment, based on popularity and market availability, researched the cost of each type at 3-5 businesses that were selling them, and established an average cost of each equipment category based on these factors. All prices were checked in mid-February 2022.

⁵ With regard to hospital capacity (bed number), survey respondents identified themselves using the following ranges: 0-50 Beds; 50-150 Beds; 151-200 Beds; 201-300 Beds; 301-400 Beds; 401-500 Beds; and 600 Beds.

⁶ N95 filtering facepiece respirators, powered air-purifying 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.

The Division estimates the cost per N95 to be approximately \$1.12. Division staff researched the cost of N95s manufactured by 3M (Model 8210) and BYD. The Division found seven businesses selling these items at a cost between \$.90 and \$1.35 per unit.⁷

The Division estimates the cost per PAPR to be approximately \$1100.60.⁸ Division staff researched the cost of PAPR systems manufactured by 3M (Versaflo TR 300N+HKL), Dover (Sentinel XL HP), and Allegro (EZ Air Tyvek). The Division found 11 businesses selling these items at a cost between \$993.75 and \$1217.94 per unit.⁹

The Division estimates the cost per elastomeric respirator to be approximately \$17.88. Division staff researched the cost of elastomeric respirators manufactured by 3M (1/2 mask 6000) and Honeywell (North 5500 1/2 mask). The Division found 8 businesses selling these items at a cost between \$15.45 and \$22.19.¹⁰

The Division estimates the cost per surgical mask to be approximately \$.50. Division staff researched the cost of surgical masks of the following three makes and models: Medline Level 1 Anti-Fog (NON27371a), Altor Level 2 (62232), Medline Level 3 Anti-Fog (NON27710). The Division found 9 businesses selling these items at a cost between \$.20 and \$.93.¹¹

The Division estimates the cost per isolation gown to be approximately \$1.76. Division staff researched the cost of isolation gowns of the following three models: Isolation Gown - Level 2 ANSI/AAMI, SMS Isolation Gown - Level 3 ANSI/AAMI, SMS Isolation Gown - Level 4 ANSI/AAMI. The Division found 10 businesses selling these items at a cost between \$.79 and \$2.95.¹²

⁷ The businesses selling the 3M Model 8210 were Grainger (\$1.35), Industrial Safety (\$.90), Envirosafety (\$.99) and Amazon (\$1.19). The businesses selling the BYD N95 were Amazon (\$.92), Costco (\$1.25) and Project N95 (\$1.25). Price per unit was based on a box of 20 units.

⁸ PAPR systems are reusable and it was not clear from the survey results described above whether an employer's PAPR consumption totals pertained to the systems themselves, as a whole, or just the replacement hoods needed for individual use. The replacement hoods are significantly less expensive than the systems themselves, so the Division took a conservative approach and priced out the cost of the whole system, which would include the hood as well.

⁹ The businesses selling the 3M (Versaflo TR 300N+HKL) were Industrial Safety (\$1,055.00), Envirosafety (\$1,049.99), Zoro (\$1,142.78), Jendco (\$999.95) and Premier Safety (\$1,177.40).

The businesses selling the Dover (Sentinel XL HP) were Grainger (\$1,214.00), Jendco Safety (\$999.99) and Abatix (\$1,217.94). The businesses selling the Allegro (EZ Air Tyvek) were Amazon (\$1,041.30), Jendco Safety (\$1,215.00), and PK Safety (\$993.75). Price per unit was based on one PAPR system.

¹⁰ The businesses selling the 3M respirators (1/2 mask 6000) were Grainger (\$22.19), Industrial Safety (\$18.75), Zoro (\$15.45) and PK Safety (\$16.22). The businesses selling the Honeywell respirators (North 5500 1/2 mask) were Grainger (\$20.84), Amazon (\$16.85), Zoro (\$15.86) and Airgas (\$16.85).

¹¹ The businesses selling the Medline Level 1 Anti-Fog (NON27371a) were Devine (\$.33), Medline (\$.35), and Medical Supply Pros (\$.33). Price per unit for each was based on a box of 300 units. The businesses selling the Altor Level 2 (62232) were Grainger (\$.26), Amazon (\$.44), and Zoro (\$.20). Price per unit was based on a box of 50 units. The businesses selling the Medline Level 3 Anti-Fog (NON27710) were Medline (\$.88), Medical Supply Pros (\$.82) and Health Products For You (\$.93). Price per unit was based on a box of 100 units.

¹² The businesses selling the Level 2 gowns were Sunline (\$.79), MedEquip Depot (\$1.37), Respiratory Care Store (\$1.21) and Wilburn Medical (\$1.43). Price per unit was based on a box of 300 units, except for Sunline, which was a box of 150 units. The businesses selling the Level 3 gowns were Sunline (\$1.97), Amazon (\$1.20), and USA Medical (\$1.78). Price per unit was based on a box of 50 units for Sunline, 200 units for Amazon, and 100 units from USA Medical. The businesses selling the Level 4 gowns were Sunline (\$2.95), Amazon (\$1.99), and USA

The Division estimates the cost per eye protection to be approximately \$5.77. Division staff researched the cost of the following two eye protection models: Honeywell Uvex S360 and Honeywell Uvex A705. The Division found 6 businesses selling these items at a cost between \$3.43 and \$9.04.¹³

The Division estimates the cost per eye protection to be approximately \$.38. Division staff researched the cost of the following two shoe covers: Dupont Tyvek 400 and Lakeland CTL901. The Division found 6 businesses selling these items at a cost between \$.24 and \$.58.¹⁴

The average costs of one unit of each of the seven (7) specified categories of equipment, using the foregoing price points and methodology, are as follows:

N95s	PAPRs	Elastomeric	Surgical Masks	Isolation Gowns	Eye Protection	Shoe Covers
\$1.12	\$1,100.60	\$17.88	\$0.50	\$1.76	\$5.77	\$0.38

Based on the estimated cost per item of specified equipment and the number of additional units of specified equipment that the population of 360 private hospitals would be required to amass to bring their stockpile into compliance under the regulatory definition, the total additional costs of equipment that would be incurred by private general acute care hospitals was calculated to be \$5,165,423.00.

Based on the estimated cost per item of specified equipment and the average cost of additional equipment required per hospital, by capacity, the average additional equipment costs per private hospital was calculated to be \$11,280.00.

Cost Adjustment to Reflect Potential 2021 Consumption Total Increase:

As specified above, foregoing calculations were based on 2019 and 2020 consumption totals and thus reflect the costs that employers would incur to bring their stockpiles into compliance under the regulatory definition in the year 2021. The costs that employers will incur to bring their stockpiles into compliance at the time that the proposed regulation would go into effect, Fall 2022, may be higher if a hospital’s consumption totals increased in 2021.

Under the proposed regulation, because of the 200% cap on 2nd year consumption totals, the most that a stockpile can increase from year to year is by 150%. For the purposes of calculating costs that will be incurred at the time that the proposed regulation goes into effect in Fall 2022,

Medical (\$2.91). Price per unit was based on a box of 50 units from Sunline, 10 units from Amazon and 65 units from USA Medical.

¹³ The businesses selling the Honeywell Uvex S360 were Industrial Safety (\$6.99), Full Source (\$6.79) and Airgas (\$9.04). The businesses selling the Honeywell Uvex A705 Grainger (\$4.83), Amazon (\$3.56), and Zoro (\$3.43). Prices per unit based on one unit each.

¹⁴ The businesses selling the Dupont Tyvek 400 were Enviro Safety (\$.39), Amazon (\$.58) and Jendco Safety (\$.52). The businesses selling the Lakeland CTL901 were Enviro Safety (\$.24), Zoro (\$.30), and Jendco Safety (\$.25). Prices per unit based on one unit each.

the Division took the most conservative approach and assumed the maximum 150% increase from 2020 to 2021.

Assuming a 150% increase in consumption totals in each category of specified equipment in 2021, the total cost of the additional amounts of the seven categories of specified equipment required to bring all 360 private general acute care hospitals into compliance under the proposed regulation in the year 2022 would be \$7,748,135.00. The estimated average additional equipment cost for a representative private general acute care hospital to bring its statutory stockpile into compliance under the proposed regulation in the year 2022 would be \$16,920.00.

Calculation of Storage Costs:

In addition to the costs incurred by an employer for additional equipment needed to bring its stockpile into compliance under the regulatory definition, employers may also incur costs to store the additional equipment.

The exact storage capacity of individual hospitals is unknown. Where additional storage space of 60 square feet or less would be required for the additional equipment procured to bring a stockpile into compliance under the proposed regulation, it is presumed that, particularly given the size of the facilities at issue and the amount of storage required to store the facility’s pre-existing equipment stockpiles, the amount of additional space needed was marginal and could be accommodated by the facility’s existing storage capacity.

Where more than 60 additional square feet would be required, although facilities of these sizes would like be able to accommodate that need with existing resources, the Division nevertheless calculated the yearly cost of a storage facility for the additional equipment.

Average Additional Storage Costs Per Hospital, By Capacity, And Total For 360 Private General Acute Care Hospital Population

Hospital Bed Count	Total Square Footage Needed for Additional Equipment ¹⁵	Total Storage Cost ¹⁶	# of Private Hospitals In This Bed Count Range	Total Storage Costs for 360 Private Hospitals
0-50	1	De minimus	68	De minimus
51-150	23	De minimus	123	De minimus
151-200	51	De minimus	33	De minimus
201-300	1	De minimus	59	De minimus

¹⁵ All package dimensions and number of units per equipment package type were provided by the Division of Occupational Safety and Health’s Calibration and Inventory Control (CALICO) Laboratory. In each category, the number of additional units of each equipment category that was required was divided by the number of units per package, to determine the number of packages needed. That total was then multiplied by the square footage of the package to determine total square footage needed. Those amounts were then multiplied by 150% to determine the highest amount of square footage that would be needed in the year 2022, when the regulation would go into effect.

¹⁶ The Division hired a consulting firm to do market research on the cost of storage space in various locales. Average annual off site storage costs were \$20/sq ft in urban areas, \$12/sq ft in suburban areas and \$6/sq/ft in rural areas of the state, for an estimated statewide average of \$13/sq ft.

301-400	32	De minimus	42	De minimus
401-500	320	\$4160	26	\$108,160
501-600	96	\$1248	5	\$6240
600+	32	De minimus	4	De minimus

The total additional storage costs per year for private general acute care hospitals would be approximately \$114,400.

The estimated average storage costs per private hospital are \$318.00

Future Annual Costs:

If consumption totals remain stable or decline, an employer will not incur additional equipment costs under the proposed regulation because if the annual consumption totals do not increase, neither will the overall required size of the stockpile under the regulatory definition. Once the stockpile is brought into compliance, it must be “maintained” at that level, pursuant to the requirements of Labor Code 6403.3(c). The costs to an Employer to maintain its stockpile at existing levels would only include the replacement costs that would arise depending upon equipment usage rates. Such replacement costs would be incurred under the statutory stockpile requirement, regardless of the instant proposed regulation. Thus, under circumstances where consumption levels have not increased beyond the totals from the preceding year, the only costs an affected employer would incur under the proposed regulation would be continuing storage costs, if any.

The Division cannot predict future consumption levels, however, with regard to the current Covid-19 pandemic, it is reasonable to expect that consumption levels will likely stabilize, yet remain elevated in amounts consistent with 2021 consumption levels, in 2022. For this reason, the Division built into its calculations the 150% cost increase described above.

It is also reasonable to expect that beginning in 2023 and beyond, consumption totals will likely remain stable, as the current pandemic shifts into an endemic phase, or begin to decrease towards pre-pandemic levels. Because it is not expected that consumption totals will continue to increase after the year 2022, the additional equipment costs incurred by affected employers under the proposed regulation after that year would be de minimus. The only continuing costs would be the storage costs, if any, required to accommodate the additional equipment amounts described above.

The total costs that would be incurred by private business would be an initial cost of \$7,862,535.00 with ongoing costs of \$114,400.00 per year.

Creation or Elimination of Jobs Within the State of California Or Creation of New Business, Elimination of Existing Business, or the Expansion of Business In California:

The annual cost for a typical private general acute care hospital would be \$17,238.00 in the first year and \$318.00 in continuing annual costs. For the discrete category of businesses affected by this proposed regulation, general acute care hospitals, these costs are marginal compared to not

only the overall costs of PPE required for daily use, but hospital operations as a whole. As such, the proposed regulation should not result in any changes to hiring practices within existing companies or to the number or size of businesses in the state. The Division does not anticipate that there would be sufficient economic impact to reduce the number of general acute care hospitals in the state or to create new businesses to address requirements created by the proposal.

The total statewide savings that would result from the proposed regulation cannot be quantified. If healthcare workers have sufficient levels of protective equipment, there will be fewer disruptions to patient care caused by the need to preserve equipment or by the absence of healthcare workers due to illness. The number, frequency and extent of future surge events, however, are unknown and there is little data distinguishing deaths/illnesses of healthcare workers from occupational exposure as opposed to exposures from other sources. Although the benefits cannot be quantified, ensuring sufficient protective equipment is available in the event of a surge event, whether created by an illness or otherwise, will result in improved health for California health care workers and reduce the financial costs caused by medical care and lost workdays, costs which may be borne by employees, their families, employers, insurers and public benefits programs.

Benefits of the Proposed Rulemaking to the Health and Welfare of California Residents, Worker Safety, and the State’s Environment:

The regulation will provide employers with clear direction as to what their obligations are under the Labor Code 6403.3(c) stockpile requirement, so that they can in turn satisfy that requirement, and it will enable the Division to consistently and uniformly enforce the requirement. This will result in heightened occupational safety and health for impacted hospital workers.

The 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. It 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. This will reduce the financial costs caused by medical care and lost workdays.

Additionally, minimizing exposures and resulting illnesses of healthcare workers will help reduce transmissions 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 or any subsequent infectious disease for the public at large.

This regulation is expected to be neutral to and will provide neither a benefit nor a detriment to the state’s environment.

EVIDENCE SUPPORTING FINDING OF NO SIGNIFICANT STATEWIDE ADVERSE IMPACT DIRECTLY AFFECTING BUSINESS:

The Division has made an initial determination that this proposal will not result in a significant, statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

The proposed regulation is not a new requirement but rather defines a term used in an existing obligation. The scope of businesses potentially economically impacted by the regulation is very narrow – approximately 415 general acute care hospitals. The hospitals affected by this regulation are already required to stockpile specified equipment in compliance with Labor Code section 6403.3(c). The average costs that would be incurred per hospital are approximately \$17,238.00. Generally speaking, the additional costs incurred by each hospital is proportionate to its size, with smaller hospitals incurring lower additional equipment and storage costs and vice versa. For each hospital, such costs are marginal in comparison to the costs incurred for daily PPE usage, let alone total operational costs of the business. As such, the Division does not believe that the additional costs created by the proposed regulation will adversely economically impact these businesses or impact their ability to compete.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDIES, REPORTS OR OTHER DOCUMENTS RELIED ON

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

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. 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 February 18, 2022, <https://www.cdph.ca.gov/Programs/OPA/Pages/NR22-037.aspx>
3. California Department of Public Health, “State Public Health Officer Order of August 16, 2021, <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Order-of-the-State-Public-Health-Officer-Hospital-and-Health-Care-System-Surge.aspx>
4. Table of Survey Responses Received From California Hospital Association
5. California Department of Public Health, Center for Health Care Quality, Licensing and Certification (L&C) Program, Table of Healthcare Facility Locations, accessed February 22, 2022, https://data.chhs.ca.gov/dataset/3b5b80e8-6b8d-4715-b3c0-2699af6e72e5/resource/098bbc36-044d-441f-9442-1f4db4d8aaa0/download/healthcare_facility_locations.xlsx

These documents are available for review Monday through Friday from 8:00 am to 4:40 pm at the Division of Occupational Safety and Health located at 1515 Clay Street, Suite 1901, Oakland, CA 94612.

ADVISORY COMMITTEE

An advisory committee meeting was held in February 2021 before the emergency regulation was promulgated.

REASONABLE ALTERNATIVES TO THE REGULATON AND THE DIVISION’S REASON FOR REJECTING SUCH ALTERNATIVES.

The Division has considered the following alternatives:

Alternative 1: Normal Consumption Defined As Average Amount of Specified Equipment Consumed Over Most Recent Two Year Period Excluding Periods Where State of Emergency Due to Pandemic is Declared.

Under this alternative, normal consumption would be defined as the average quantity of each category, type and size of the specified equipment consumed during the preceding two calendar years, with the exception of any periods when a state of emergency due to pandemic conditions affecting the area where the facility is located is declared by the Governor pursuant to its authority under Government Code section 8625. It would be calculated by determining the average monthly quantity of each category, type and size of the specified equipment consumed in the facility during the non-emergency periods and multiplying it by three.

Using the data provided from the existing sample of 55 hospitals for 2019 consumption totals in each category¹⁷ and extrapolating that out to the 415 general acute care hospitals, the cost of this alternative would be approximately \$2,258,885.00.

This alternative would not accurately reflect the reality that natural variations in consumption levels, including large fluctuations created by surge conditions, occur over time based on fluctuations in demand. It would lead to an unquantifiable decrease in the amount of each category of specified equipment that employers are required to stockpile. This, in turn, would lead to an unquantifiable increase in the likelihood that hospitals would not have sufficient equipment levels to protect healthcare workers in the event of a surge. Under this alternative, the benefits to occupational safety and health would be lower than under the proposed regulation.

While this alternative would be more cost-effective than the proposed regulation, it would be significantly less effective than the proposed regulation in carrying out its protective purpose. For this reason, the Division has rejected this alternative at this time.

Alternative 2: Normal Consumption Defined As Average Amount of Specified Equipment Consumed Over Previous Two Year Period.

Under this alternative, the 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, as defined, over the previous two-year period. It would remove the 200% cap on the quantity used to represent consumption during the *second year* when that year's consumption total amounts to more than 200% of the *first year* consumption total. As such, there would be no mechanism in place to account for unusually extreme or high consumption totals that could unreasonably skew the average two-year demand for equipment.

¹⁷ These numbers are based on consumption totals from January 2019 through December 2019. A state of emergency was declared in California on March 4, 2020. Thus, data from the first two months of 2020 would be included in an employers' calculations under this definition – it would include consumption totals from February 2019 through February 2020. However, because monthly consumption data for January and February 2020 were not available to the Division, the first two months in 2019 were used as a proxy for the first two months of 2020.

The cost of this alternative would be significantly higher than that of the proposed section 340.70. Using the data provided from the existing sample of 55 hospitals for 2019 and 2020 consumption totals in each category and extrapolating that out to the 415 general acute care hospitals, the cost of this alternative would be approximately \$19,602,764.00.

This alternative would lead to an unquantifiable increase in the amount of specified equipment that employers would be required to stockpile and an unquantifiable decrease in the likelihood that hospitals would not have sufficient equipment levels to protect healthcare workers in the event of a surge. Under this alternative, the benefits to occupational safety and health would likely be higher than under the proposed regulation.

While this alternative would be more protective than the proposed regulation in carrying out its protective purpose, it would not only be significantly more costly but it would also be significantly more strategically burdensome for affected employers to procure and maintain the stockpile amounts that would be required. It could require extreme jumps in the required stockpile amount from year to year, making planning significantly more difficult for general acute care hospitals. For this reason, the Division has rejected this alternative at this time.