

INITIAL STATEMENT OF REASONS

SUMMARY OF THE PROPOSAL

These regulations will implement new minimum staffing requirements for skilled nursing facilities (SNFs) as established by Senate Bill (SB) 97 (Chapter 52, Statutes of 2017). This regulatory action is necessary to comply with language in the legislation directing the California Department of Public Health (Department) to adopt regulations to implement the amendments made by SB 97.

POLICY STATEMENT OVERVIEW

Problem Statement: SB 97 increased the minimum staffing standard for SNFs from 3.2 nursing hours per patient day (NHPPD) to 3.5 direct care service hours per patient day (DCSHPPD), with a minimum of 2.4 hours per patient day performed by certified nurse assistants (CNAs). This regulatory action is necessary to implement these new minimum staffing requirements and to make permanent the emergency regulations that became effective on July 1, 2018.

Objectives: The broad objectives of this proposed regulatory action are:

- To fulfill the legislative directive to adopt regulations to implement the amendments made by SB 97.
- To align the Department's regulations with changes to statute.

Benefits: The expected benefits of this proposed regulatory action are:

- To improve clarity and reduce confusion within the regulated community and for residents and their families by aligning the staffing standards in the Department's regulations with the standards set by the Legislature.

BACKGROUND/AUTHORITY

The Department is authorized to adopt, amend, or repeal regulations pursuant to Health and Safety Code sections 1276.5,¹ 1276.65, 1275, and 131200 as may be necessary for the execution of its duties. Pursuant to section 131051, subdivision (b)(5), the Department is responsible for licensing SNFs. As part of its licensing duties, the Department audits SNFs to determine compliance with minimum staffing requirements. Prior to July 1, 2018, the minimum staffing standard was 3.2 NHPPD. (§ 1276.5, subd. (a).) The NHPPD were calculated by dividing the total number of nursing hours performed by direct caregivers in a 24-hour period by the resident² census during that period.

Senate Bill 97 increased the minimum staffing standard and revised the terminology from the NHPPD standard to the DCSHPPD standard. As of July 1, 2018, all

¹ All further statutory references are to the Health and Safety Code unless otherwise indicated.

² For the purposes of this ISOR, the terms patient and resident are used interchangeably to describe a person who resides in a SNF. While the term resident is preferred, some provisions of law still refer to these persons as patients.

freestanding SNFs, excluding distinct parts of general acute care hospitals, state-owned hospitals, or developmental centers, must increase staffing from 3.2 NHPPD to 3.5 DCSHPPD, with a minimum of 2.4 hours per patient day performed by CNAs. (§ 1276.65, subds. (c)(1)(B)-(C).) Direct care service hours are defined as the actual hours of work performed per patient day by a direct caregiver. (§ 1276.65, subd. (a)(1).) A direct caregiver means a registered nurse, a licensed vocational nurse, a psychiatric technician, a CNA, or a nurse assistant participating in an approved training program, while performing nursing services. (§ 1276.65, subd. (a)(2).)

Senate Bill 97 directed the Department to adopt emergency regulations to implement the new direct care service hour requirements, in consultation with stakeholders. (§ 1276.65, subd. (c)(1)(D).) To engage stakeholders and promote transparency in the development of the emergency regulations, the Department solicited written comments and hosted a series of four public stakeholder forums between October 2017 and February 2018. The Department considered the comments received both in writing and at the stakeholder forums in the development of the emergency regulations.

The emergency regulations became effective on July 1, 2018. In July 2018, the Department again solicited written comments and hosted two additional stakeholder forums to discuss next steps, including development of these permanent regulations. The Department now seeks to promulgate permanent regulations via the regular rulemaking process.

Implementation of the new staffing requirements, as well as these regulations, is contingent on an appropriation in the annual Budget Act and continued federal approval of the Skilled Nursing Facility Quality Assurance Fee pursuant to Health and Safety Code division 2, chapter 2, article 7.6 (commencing with section 1324.20). (§ 1276.65, subd. (i).) The Budget Act for fiscal year 2018-19 included funding for these provisions.

AUTHORITY AND REFERENCE

Authority: Sections 1275, 1276.5, 1276.65, and 131200, Health and Safety Code.

Reference: Sections 1276, 1276.5, 1276.65, 131050, 131051, and 131052, Health and Safety Code; and section 14126.022, Welfare and Institutions Code.

SPECIFIC RATIONALE FOR EACH SECTION

The specific purpose of each amendment, the problem the Department intends to address, and the rationale for the determination that each amendment is reasonably necessary to carry out the purpose and address the problem for which it is proposed is as follows:

Section 72329.2, subdivision (a)(1).

This proposed regulation implements the new DCSHPPD requirements for SNFs. The Department proposes to adopt the requirements set out in section 1276.65, subdivisions (c)(1)(B) and (c)(1)(C), rather than adopting higher minimum staffing standards. At this

time, the Department believes that the staffing requirements set forth by the Legislature represent a balance between ensuring resident safety and establishing minimum requirements that can reasonably be achieved by facilities. The Department will evaluate the impact and effectiveness of these new minimum requirements, as required by SB 97, to determine their impact on resident quality of care. (§ 1276.65, subd. m.) Regardless of the minimum requirements, facilities are still required to employ and schedule sufficient staff to ensure quality resident care based on the needs of residents. (§ 1276.65, subd. (d).) Resident needs may necessitate staffing above the minimum requirements some or all of the time.

This proposed regulation also restates the statutory exemptions to these minimum staffing requirements found in section 1276.65, subdivision (c)(1)(B), and clarifies that distinct part SNFs are still required to meet the 3.2 NHPPD standard set forth in section 1276.5. The Legislature did not amend the 3.2 NHPPD standard in section 1276.5, so that standard still applies to distinct part SNFs. This regulation is reasonably necessary to align the Department's regulations with statute, improve clarity, and reduce confusion.

Section 72329.2, subdivisions (a)(2)(A) and (B).

These proposed regulations clarify that the new 3.5 and 2.4 DCSHPPD requirements do not always apply in SNFs that provide care for persons with mental health disorders. For patients certified for special treatment programs, SNFs are held to a different staffing standard. A special treatment program service unit distinct part is an identifiable and physically separate unit of a SNF or an entire SNF that provides therapeutic programs to an identified population group of persons with mental health disorders. (§ 1276.9, subd. (b).) A special treatment program service unit distinct part is required to provide a minimum of 2.3 NHPPD. (§ 1276.9, subd. (a).) This proposed regulation is consistent with statute and reasonably necessary to reduce confusion about the applicable staffing requirements in SNFs that serve persons with mental health disorders.

Section 72329.2, subdivisions (b)(1)(A) and (b)(1)(B).

These proposed regulations establish the process for a facility to apply for the waiver authorized by section 1276.65, subdivision (c)(2). Subdivision (c)(2) authorizes SNFs to apply for a waiver that addresses individual patient needs, except that in no instance shall the facility fall below 3.5 direct care service hours per patient day. (§ 1276.65, subd. (c)(2).) This waiver is known as the patient needs waiver. If granted, this waiver permits a facility to waive the requirement to provide a minimum of 2.4 direct care service hours for CNAs. However, the facility is still required to provide an overall minimum of 3.5 DCSHPPD.

The Department will use an online portal through which facilities will be able to attach and submit the documents that make up the application, as required by this proposed regulation. The Department must receive all patient needs waiver applications by April 1 of each year to ensure sufficient time to process the applications prior to June 30. By

June 30 of each year, the Department must notify the Department of Health Care Services (DHCS) which SNFs participating in the Medi-Cal program have an approved patient needs waiver. DHCS must have this information so it can set its Medi-Cal reimbursement rates for the coming rate year, as these rates take into account whether a facility has an approved waiver.

The Department proposes to establish two sets of application requirements for facilities applying for a patient needs waiver. The first would apply to facilities that do not have a subacute care unit³ approved by the Department of Health Care Services (DHCS) and to facilities seeking to waive the 2.4 CNA hours per patient day requirement for the non-subacute portion of a facility that provides subacute and non-subacute care. The second would apply to facilities seeking to waive the 2.4 CNA hours per patient day requirement for a subacute unit approved by DHCS.

These two waiver application processes are reasonably necessary because the needs of subacute care patients differ from the needs of non-subacute care patients. Subacute care is available to patients who meet certain criteria as defined by DHCS. These patients are medically fragile and require special services, such as inhalation therapy, tracheotomy care, intravenous tube feeding, and complex wound management care. Many of these special services must be performed by licensed nurses and cannot be performed by CNAs. As a result, subacute care units are already subject to minimum staffing requirements established by DHCS that emphasize licensed nursing care. Subacute care units in freestanding SNFs must provide a minimum daily average of 3.8 licensed nursing hours per patient day and 2.0 CNA hours per patient day in the subacute unit, for a total of 5.8 hours per patient day. (Cal. Code Regs., tit. 22, § 51215.5, subd. (e).) Thus, being an approved subacute care unit supports a facility's request for a patient needs waiver for that unit. Having the facility submit its contract with DHCS and its most recent staffing audit findings from DHCS with its request for a patient needs waiver provides sufficient documentation to justify the request.

For facilities without a subacute care unit or for the non-subacute portion of a facility with both subacute and non-subacute care units, a facility must submit more detailed information to support a waiver request. There are four (4) specific pieces of information that are illustrative of non-subacute care patient needs and demonstrate a facility's ability to provide for those needs:

- The average daily census at the facility, excluding any patients in an approved subacute care unit;
- The facility's Minimum Data Set (MDS) Facility Level Quality Measure Report and Minimum Data Set Facility Characteristics Report, dated no earlier than 30 days prior to submission of the waiver application;

³ A subacute care unit is an identifiable unit of a SNF accommodating beds including contiguous rooms, a wing, a floor, or a building that is approved by DHCS for such purpose. (Cal. Code Regs., tit. 22, § 51215.5, subd. (a).)

- The level of direct caregiver staffing the facility will provide if granted a waiver, including the number and type of staff; and
- An analysis of the resident needs at the facility, including a description of the assessment tools used, how the tools were applied, and the outcomes used to determine resident needs.

The average daily census and MDS reports provide an objective snapshot of the facility's current profile and resident mix. The MDS reports contain information such as the age, diagnostic characteristics, and prognosis of current residents. These reports also reflect the incidence of various quality measures, such as pressure ulcers, falls, and excess weight loss. This information is indicative of current patient needs at the facility. The Department proposes to permit facilities to submit MDS reports dated up to 30 days prior to submission of the application; this is a reasonable timeframe because it accounts for the time it may take a facility to compile and submit an application. However, the MDS reports must be dated no earlier than 30 days prior to submission of the waiver application because older reports may not be reflective of current resident needs.

While the census and MDS reports provide an overview of patient needs from a single point in time, the Department believes it is also reasonably necessary to require facilities to conduct a more in-depth analysis created specifically for the purpose of applying for a patient needs waiver. This analysis would provide a more in-depth look at the facility and illustrate why resident needs would be better served by substituting more licensed nurses for CNAs. The Department understands that each facility may have different reasons for requesting a patient needs waiver. This proposed regulation allows a facility the flexibility to describe its unique patient needs using all relevant information.

The Department cannot properly evaluate a facility's waiver request without some indication of how the facility plans to staff if granted a waiver. The application must include the number and type of direct caregiver staffing the facility plans to provide to meet its unique patient needs.

Section 72329.2, subdivisions (b)(2)(A), (B), (C), and (D).

Because patient needs vary from facility to facility, the Department will evaluate applications for patient needs waivers on a case-by-case basis. However, the Department proposes to consider four (4) broad types of information when evaluating all waiver requests. The Department believes that the substantiating information submitted by the facility and the needs and acuity levels of residents at the facility relate directly to whether the patient needs at the facility justify substituting licensed nurses for CNAs at the facility. The resident quality of care at the facility and the facility's compliance history are also indicative of patient needs at the facility and whether the facility should be granted a waiver of the specific staffing requirements established by the Legislature and adopted by the Department. This information provides a more comprehensive view of a facility seeking a patient needs waiver.

Section 72329.2, subdivision (b)(3).

This proposed regulation is reasonably necessary to ensure that the Department has current, accurate information about the patient needs at a facility. It is not reasonable to require a facility to notify the Department every time there is a change in the facility's census or MDS reports, as this information may fluctuate on a daily basis. However, patient needs may change over time to the extent that a patient needs waiver is no longer justified. If there is a change in the analysis of the resident needs at the facility, or if the facility no longer has a contract with DHCS to provide subacute care, the facility must notify the Department so the Department can reevaluate the need for the waiver.

Section 72329.2, subdivisions (b)(4), (5), (6), and (7).

These regulations would impose various procedural requirements on facilities requesting a patient needs waiver. An annual renewal requirement is reasonable so the Department can reassess whether the waiver is still appropriate, and the April 1 submission deadline is necessary for the reason stated above. Requiring renewal more frequently than annually would be overly burdensome for facilities, would be unlikely to improve resident safety, and could cause uncertainty for residents, potential residents, and their families as to whether a facility has an approved waiver at a given time. Rather, the Department proposes to require facilities to notify the Department within 15 days of the changes identified proposed subdivision (b)(3). The notice and posting requirements are reasonably necessary to ensure that all residents and their families are aware that a facility has requested or received a waiver of the minimum staffing requirements, prior to executing an admission agreement.

Section 72329.2, subdivision (b)(8).

This proposed regulation is reasonably necessary to notify facilities that the Department may revoke approval of a patient needs waiver at any time, if the facility does not comply with the terms and conditions of the waiver.

Section 72329.2, subdivision (c)(1).

This proposed regulation references the new type of waiver authorized by SB 97, known as the workforce shortage waiver. Section 1276.65, subdivision (I), directs the Department to create a waiver of the 3.5 and 2.4 direct care service hour requirements to address a shortage of available and appropriate health care professionals and direct caregivers. The Department is authorized to create this waiver via All Facility Letter (AFL), which it has done. (§ 1276.65, subd, (I).) The Department believes it is reasonably necessary to reference this waiver in the proposed regulations to ensure that SNFs seeking a waiver know where to look for the criteria. Referencing the AFL will improve clarity and reduce confusion by referencing all available waivers in the same section of law.

Section 72329.2, subdivision (d).

This proposed regulation restates section 1276.65, subdivision (i), which restricts the Department's ability to implement these regulations without a specific legislative appropriation in the annual Budget Act and continued federal approval of the Skilled

Nursing Facility Quality Assurance Fee pursuant to Article 7.6 (commencing with section 1324.20). This regulation is reasonably necessary to improve clarity and reduce confusion because someone reading this regulation may not otherwise be aware of the contingency language in section 1276.65, subdivision (i).

Section 72329.2, subdivision (e).

This proposed regulation is reasonably necessary to clarify that the Department retains its authority to continue to implement Welfare and Institutions Code section 14126.022 via AFL. This regulation is reasonably necessary to improve clarity and reduce confusion because the AFL issued pursuant to Welfare and Institutions Code section 14126.022 also relates to implementation and enforcement of DCSHPPD requirements; namely, the process for auditing SNF compliance with the requirements. The Department believes it should be clearly stated that nothing in these proposed regulations shall infringe upon that separate and concurrent statutory authority.

STATEMENTS OF DETERMINATIONS

REASONABLE ALTERNATIVES CONSIDERED

The Department has determined that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome for affected SNFs than the proposed action, or would be more cost effective for affected SNFs and equally effective in implementing the higher staffing requirements established by SB 97.

LOCAL MANDATE DETERMINATION

The Department has determined that the proposed action would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by part 7 (commencing with section 17500) of division 4 of the Government Code.

CONSISTENCY AND COMPATIBILITY WITH STATE REGULATIONS DETERMINATION

The Department evaluated whether the proposed regulations are inconsistent or incompatible with existing state regulations. This evaluation included a review of the Department's laws, as well as those statutes and regulations related to SNFs. The Department has determined that this proposed regulatory action is not inconsistent or incompatible with existing operative regulations. After conducting a review for any regulations that would relate to or affect staffing requirements in SNFs, the Department has concluded that no known statute or operative regulation conflicts with this proposed regulatory action.

ECONOMIC IMPACT ASSESSMENT/ANALYSIS

Purpose

The proposed regulations will implement new minimum staffing requirements for SNFs and document the waiver process established by SB 97 (Chapter 52, Statutes of 2017). This regulatory action is necessary to comply with language in the legislation directing the Department to adopt regulations to implement the amendments made by SB 97.

The Creation or Elimination of Jobs within the State of California

The regulations implement the new DCSHPPD requirements for SNFs found in Health and Safety Code section 1276.65, establish the process for a facility to apply for a waiver, and impose various procedural requirements on facilities requesting a waiver. Because the regulations only reiterate statutory requirements and provide procedural clarifications for SNFs seeking a patient needs waiver, the regulations will not affect the creation or elimination of jobs in California. Any new jobs created are the result of the increased staffing requirements in statute. It is unknown whether the waiver process specified in the regulations will result in additional or fewer CNA hires, depending on facility staffing and patient needs. Therefore, the Department has determined that the proposed regulations will not have a significant impact on the creation or elimination of jobs in the State of California.

The Creation of New Businesses or the Elimination of Existing Businesses Within the State of California

The regulations implement the new DCSHPPD requirements for SNFs found in Health and Safety Code section 1276.65, establish the process for a facility to apply for the waiver, and impose various procedural requirements on facilities requesting a waiver. Because the regulations only reiterate statutory requirements and provide procedural clarifications for SNFs seeking a patient needs waiver, the regulations will not affect the creation or elimination of business in California. Therefore, the Department has determined that the proposed regulations will not have a significant impact on the creation or elimination of existing businesses in the State of California.

The Expansion of Businesses Currently Doing Business within the State of California

The regulations implement the new DCSHPPD requirements for SNFs found in Health and Safety Code section 1276.65, establish the process for a facility to apply for the waiver, and impose various procedural requirements on facilities requesting a waiver. Because the regulations only reiterate statutory requirements and provide procedural clarifications for SNFs seeking a patient needs waiver, the regulations will not expand business in California. The Department is not aware of any cost impacts that a representative private person or business not seeking a patient needs waiver would necessarily incur in reasonable compliance with the regulations. Therefore, the Department has determined that the proposed regulations will not expand businesses currently operating in the State of California.

Benefits of the Regulations to the Health and Welfare of California Residents, Worker Safety, and the State's Environment

The regulations implement the new DCSHPPD requirements for SNFs found in Health and Safety Code section 1276.65, establish the process for a facility to apply for the waiver, and impose various procedural requirements on facilities requesting a waiver. The anticipated benefits to these regulations are improved clarity and reduced confusion within the regulated community and for residents and their families by aligning the staffing standards in the Department's regulations with the standards set by the Legislature.

EVIDENCE SUPPORTING NO SIGNIFICANT ADVERSE ECONOMIC IMPACT ON BUSINESS

Implementation of these proposed regulations is contingent upon an appropriation in the annual Budget Act and continued federal approval of the Skilled Nursing Facility Quality Assurance Fee, in accordance with Health and Safety Code section 1276.65, subdivision (i). The Budget Act for fiscal year 2018-19 included funding for these provisions.

The Department has made an initial determination that these proposed regulations would not have a significant statewide adverse economic impact directly impacting businesses, including the ability of California businesses to compete with businesses in other states. The 2018 Budget Act includes \$43 million (\$21.7 million General Fund) for the SNF staffing standard "add-on" to implement SB 97. The add-on reimburses SNFs participating in the Medi-Cal program for costs to increase their staffing levels to meet the new statutory mandated staffing standards. These regulations do not add any additional cost to the cost of the statutory change.

The regulations implement the new DCSHPPD requirements for SNFs found in Health and Safety Code section 1276.65, establish the process for a facility to apply for the waiver, and impose various procedural requirements on facilities requesting a waiver. These proposed regulations would have a minor economic impact on SNFs applying for a patient needs waiver to waive the requirement to staff at 2.4 direct care service hours per patient day for CNAs. The Department will use an online application process for this waiver and proposes additional administrative requirements for waiver applicants. These requirements include renewing the patient needs waiver annually, posting a notice of an approved waiver in a public location within the facility, and providing written notice of approved or pending waivers to potential residents.

IMPACT ON SMALL BUSINESS DETERMINATION

The regulations implement the new DCSHPPD requirements for SNFs found in Health and Safety Code section 1276.65, establish the process for a facility to apply for the waiver, and impose various procedural requirements on facilities requesting a waiver. Because the regulations only reiterate statutory requirements and provide procedural clarifications for SNFs seeking a patient needs waiver, the regulations will not negatively

impact small businesses. The Department is not aware of any cost impacts that a representative private person or business not seeking a patient needs waiver would necessarily incur in reasonable compliance with the regulations. Therefore, the Department has determined that the proposed regulations will have no adverse impact on small businesses.

HOUSING COSTS DETERMINATION

The Department has determined that these proposed regulations will not impact housing costs.

BUSINESS REPORTING REQUIREMENT

None.

FISCAL IMPACT ASSESSMENT

1. Fiscal impact on local government: None. The Department is not aware of any cost impacts a local government agency would necessarily incur in complying with the proposed regulations.
2. Fiscal impact on state government: None. The Department is not aware of any cost impacts that state government would necessarily incur in complying with the proposed regulations. The Department does anticipate a moderate increase in applications for patient needs waivers stemming from this regulatory proposal. However, all costs related to this regulation, including allocation of staff time to review and process any additional patient needs waivers, are expected to be part of the workload of the Department as funded in the 2018 Budget Act. The 2018 Budget Act included 15 positions in the 2018 Budget to implement SB 97. Three of these positions are for waiver application processing, and the remaining positions are for CNA application processing and additional oversight for the additional CNAs. These regulations do not modify the fiscal impact of the statutory minimum staffing requirement on the Department.
3. Fiscal impact on federal funding or state programs: None.
4. Fiscal impact on private persons or businesses directly affected: None.
5. Other nondiscretionary costs or savings imposed on local agencies: There are no known costs or savings imposed on local agencies in connection to these proposed regulations.