

FINAL STATEMENT OF REASONS

The information contained in the Initial Statement of Reasons (ISOR) at the time of the Public Notice remains unchanged with the exception of the following modifications.

Section 72329.2, subdivision (b)(1)(B)(ii): The citation in subdivision (b)(1)(B)(ii) was revised from “division 5” to “division 3” to fix a typographical error.

Section 72329.2, subdivision (b)(8): Following the 45-day public notice period, the California Department of Public Health (Department) modified the grounds for revocation of a patient needs waiver to improve clarity. The Department added language clarifying that it may revoke approval of a patient needs waiver if the facility does not comply with the terms and conditions of the waiver “and the Department determines that the non-compliance poses a significant risk to the health, safety, or welfare of patients.”

ISOR, page 4: In response to a public comment, the Department revised the third sentence of paragraph 3 to reflect correct nursing care terminology. The Department revised the sentence, “These patients are medically fragile and require special services, such as inhalation therapy, tracheotomy care, intravenous tube feeding, and complex wound management care,” to “These patients are medically fragile and require special services, such as inhalation therapy, tracheostomy care, intravenous feeding, tube feeding, and complex wound management care.”

ISOR, page 6: In conjunction with the amendment to subdivision (b)(8), the Department added additional justification language to page 6, paragraph 3, of the ISOR. The Department revised the paragraph, “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,” to “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, and the Department determines that the non-compliance poses a significant risk to the health, safety, or welfare of patients. While the Department believes it is unreasonable to revoke approval of a waiver for minor administrative technicalities, the Department must be able to immediately revoke approval of a waiver, on a case-by-case basis, if continued approval of the waiver would place patients at risk.”

ATTACHMENTS TO THE FINAL STATEMENT OF REASONS
ADDENDUM I
45-Day Public Notice
Summary of Comments and Responses to Comments Received

The Department received comments from eleven (11) commenters during the 45-day public notice period beginning October 19, 2018, and ending December 7, 2018, and one (1) commenter after the public notice period closed. The Department conducted a public hearing on December 7, 2018, at which it received one (1) oral comment. The comments below are aggregated and summarized or are responded to individually.

LIST OF COMMENTERS (WT – Written Testimony, VT – Verbal Testimony)

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| 1. Gold Country Retirement Community (GCRC), Sandra J. Haskins | WT |
| 2. Retirement Housing Foundation (RHF1), William Meert, RN | WT |
| 3. Retirement Housing Foundation (RHF2), Peter O. Peabody | WT |
| 4. Advanced Rehab Center of Tustin (ARCT), Bill Arellanes | WT |
| 5. California Advocates for Nursing Home Reform (CANHR), Michael Connors
and Patricia McGinnis | WT |
| 6. Service Employees International Union Local 2015 (SEIU), Laphonza Butler | WT |
| 7. California Nurses Association/National Nurses United (CNA/NNA),
Saskia Kim | WT |
| 8. California Association of Health Facilities (CAHF), Patti Owens | WT |
| 9. Office of the State Long-Term Care Ombudsman (LTCO), Joseph Rodrigues | WT |
| 10. Service Employees International Union Nurse Alliance of California
(SEIU-NAC), Katherine Hughes, RN | WT |
| 11. California Attorneys, Administrative Law Judges and Hearing Officers
in State Employment Labor Relations (CASE), Katherine E. Regan | WT |
| 12. LeadingAge (LA), Jedd Hampton | VT |

1. COMMENT SUBJECT: 3.5 DIRECT CARE SERVICE HOURS PER PATIENT DAY (DCSHPPD) STAFFING REQUIREMENT

Comment: The Department should meet with stakeholders to consider the adequacy of the skilled nursing facility (SNF) staffing requirements and set standards that ensure high quality care for residents. The Department did not seek discussion on the adequacy of the minimum staffing standards.

Commenter(s): CANHR

Response: No change was made in response to these comments. The Department conducted extensive stakeholder engagement during the development of both the emergency and permanent regulations. This included three in-person stakeholder meetings between November 2017 and March 2018 and two in-person stakeholder meetings in July 2018. The Department also invited stakeholders to submit written comments on numerous occasions between August 2017 and July 2018. The

Department solicited input on all aspects of SB 97 implementation, including the 3.5 DCSHPPD staffing requirement. Stakeholders had the opportunity to raise concerns about the adequacy of the minimum requirements established by the Legislature. The Department created a webpage related to implementation of SB 97, where it posted meeting minutes, pre-public notice written submitted comments, documents related to implementation such as AFLs and lists of waiver applicants, and information on how to submit additional comments and questions. The Department complied with the statutory requirement to consult with stakeholders prior to promulgation of the regulations. As required by Health and Safety Code section 1276.65, subdivision (m),¹ the Department will evaluate the impact of the new minimum staffing requirements regarding resident quality of care, workforce availability, and effectiveness of the requirements.

Comment: The Department should increase the minimum staffing requirements to a level that assures high quality care for residents and enforce those requirements. It is unclear how the Department concluded 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.

Commenter(s): CANHR

Response: No change was made in response to these comments. Adequate data is not available to pinpoint a specific minimum standard above that established by the Legislature that would achieve specific improvements in quality of care. Without data to support a specific minimum above the 3.5 DCSHPPD standard, such an increase would be arbitrary and would not be reasonable. As required by section 1276.65, subdivision (m), the Department will evaluate the impact of the new minimum staffing requirements regarding resident quality of care, workforce availability, and effectiveness of the requirements.

Comment: It has been difficult to find and locate properly prepared staff for the 3.5 DCSHPPD regulatory requirement. The Department should revisit this requirement and look at alternative ways to enforce improved resident outcomes besides this regulation.

Commenter(s): ARCT

Response: No change was made in response to this comment. Presumably, the commenter is requesting that the Department reduce the minimum staffing requirements below 3.5 DCSHPPD or 2.4 certified nurse assistant (CNA) hours per patient day or delay implementation of this new standard. The Department is required by statute to adopt regulations to implement the minimum staffing requirements established by the Legislature. (§ 1276.65, subd. (c)(1)(D).) The Department cannot establish a standard below the statutory minimum and cannot delay the July 1, 2018, effective date established by the Legislature. The Department has implemented a phase-in of administrative penalties as authorized by statute. (§ 1276.65, subd. (g)(2).) Facilities facing a shortage of available direct caregivers may apply for a workforce shortage waiver as authorized by section 1276.65, subdivision (I).

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

2. COMMENT SUBJECT: 2.4 CNA HOURS PER PATIENT DAY STAFFING REQUIREMENT

Comment: The regulations should permit hours worked by nursing assistants (NAs) in approved training programs to be counted as CNA hours because:

- NAs are required to attend the same 16-hour orientation upon hire as a CNA.
- NAs have to complete 16 hours of specified training content prior to having any direct resident content.
- Upon completion of these 32 hours, NAs provide the same level and type of care that a CNA provides.

Commenter(s): CAHF

Response: No change was made in response to this comment. SB 97 requires SNFs to have “a minimum of 2.4 hours per patient day for certified nurse assistants.” (§ 1276.65, subd. (c)(1)(C).) State law defines a “certified nurse assistant” as a person who is certified by the Department as having completed the requirements of Health and Safety Code section 1337 *et seq.*, which include successful completion of a precertification training program, a competency examination, and a criminal background clearance. (§ 1337, subd. (d)(3).) In contrast, a “nursing assistant” is an unlicensed aide, assistant, or orderly who has not completed some or all of the requirements for CNA certification. (§ 1337, subd. (d)(1).) CNAs and NAs are two distinct classifications of caregivers, and SB 97 does not indicate that NAs may substitute for CNAs.

3. COMMENT SUBJECT: STAFF-TO-PATIENT RATIOS

Comment: The Department must convert the 3.5 DCSHPPD requirement into staff-to-patient ratios for direct caregivers and licensed nurses. The Department cannot abandon staff-to-patient ratios because the ratios are still required under SB 97. The Department should adjust the existing ratios in title 22, California Code of Regulations, section 72329.1, upward to meet or exceed the new staffing requirements. The legislative intent behind section 1276.65, subdivision (c), has always been to require minimum staffing requirements be set forth as ratios of patients per direct caregiver, so that residents, residents’ families, facility employees, state inspectors, and others may assist in ensuring compliance with the law. SB 97 retained that intent by retaining the mandate to establish staff-to-patient ratios in section 1276.65, subdivision (c)(1)(A), and amending subdivision (c)(2) to require that the new ratios not be less than 3.5 DCSHPPD. One commenter states: “We do not believe that any further appropriation is necessary to implement the staff-to-patient ratios, but, if the Department disagrees, it should pursue it with the Legislature.”

Commenter(s): CANHR, LTCO

Response: No change was made in response to these comments. SB 97 repealed language in section 1276.65 related to the development and implementation of staff-to-patient ratios, evidencing clear intent to move away from the concept of ratios and towards an overall staffing standard. In lieu of ratios, the Legislature directed the

Department to implement the new direct care service hour requirements. (§ 1276.65, subds. (c)(1)(D), (d), (i).) The DCSHPPD standard is a new metric separate and distinct from the previous nursing hours per patient day (NHPPD) standard and its associated staff-to-patient ratios.

While the Legislature did not uniformly repeal all references to staff-to-patient ratios in section 1276.65, it did delete key references to ratios, created the new 3.5 DCSHPPD and 2.4 CNA hours per patient day staffing standards, and did not direct the Department to develop new ratios based on the DCSHPPD standards. Each of these facts is evidence of legislative intent to disassociate the new DCSHPPD standards with ratios.

Amendments to section 1276.65, subdivisions (d) and (i), signal that the Department is to replace the old staff-to-patient ratios with the new 3.5 and 2.4 DCSHPPD requirements. SB 97 amended the phrase, “The staffing ratios to be developed pursuant to this section shall be minimum standards only” to “The direct care service hour requirements to be developed pursuant to this section shall be minimum standards only.” (§ 1276.65, subd. (d).) The Legislature also deleted the phrase “staffing ratio” from subdivision (i) and replaced it with “staffing standard.” SB 97 amended the phrase “Initial implementation of the staffing ratio developed pursuant to the requirements set forth in this section...” with “Implementation of the staffing standard developed pursuant to the requirements set forth in this section....” (§ 1276.65, subd. (i).)

Notably, SB 97 did not amend section 1276.65, subdivision (c)(1)(A), to direct the Department to establish staff-to-patient ratios by a future date. That subdivision continues to state that the Department shall develop regulations that become effective August 1, 2003, that establish staff-to-patient ratios. The Department previously developed the regulations required by that subdivision; this provision is now outdated and outside the scope of the Department’s rulemaking authority. Because SB 97 did not impose a new requirement to convert the new 3.5 and 2.4 requirements under section 1276.65 into staff-to-patient ratios, the Department cannot infer such an intent.

The first sentence of section 1276.65, subdivision (c)(2), is similarly outdated and inapplicable. That sentence still directs the Department to develop staff-to-patient ratios by converting the requirements under Health and Safety Code section 1276.5 and Welfare and Institutions Code section 14110.7, statutes that still contain the 3.2 NHPPD standard. Reference to these statutes cannot be used to infer that the new DCSHPPD standard must be converted into ratios. For these reasons, the Department believes that the existing staff-to-patient ratios are incompatible with implementation of the amendments made by SB 97.

Despite the commenters’ assertions about the necessity of an appropriation, the pre-SB 97 version of section 1276.65, subdivision (i), contained a provision limiting the Department’s ability to implement the staff-to-patient ratios without a specific Legislative appropriation: “Initial implementation of the staffing ratio developed pursuant to the requirements set forth in this section shall be contingent on an appropriation in the

annual Budget Act or another statute.” The intent is clear in AB 1075: “This bill would make the implementation of the staffing ratio requirements set forth in the bill contingent on an appropriation in the annual Budget Act or other statute.” (Legis. Counsel’s Dig., Assem. Bill No. 1075 (2000-2001 Reg. Sess.)) Because the Department never received the necessary appropriation, the ratios created in California Code of Regulations, title 22, section 72329.1, were never implemented.

Following SB 97, the 2018-2019 Budget Act included an appropriation for implementation of the DCSHPPD staffing requirements. However, for the reasons stated above, the statute no longer contemplates the use of staff-to-patient ratios; rather, the appropriation enables implementation of the 3.5 and 2.4 DCSHPPD standards.

4. COMMENT SUBJECT: PATIENT NEEDS WAIVER

Comment: The proposed regulations focus on a process for facilities to apply for a patient needs waiver, which could reduce the new requirement of 2.4 CNA hours per patient day without authority to do so. The Department should halt development of the patient needs waiver because SB 97 does not authorize this waiver for the purpose of waiving the 2.4 CNA hours per patient day staffing requirement. The patient needs waiver applies to staff-to-patient ratios, not the new minimum staffing requirements for CNAs. Section 1276.65, subdivision (c)(2), directs the Department to develop a waiver procedure for staff-to-patient ratios. This waiver has nothing to do with the 2.4 CNA hours requirement, and there is no legislative history on SB 97 to support the Department’s position that the patient needs waiver applies to the 2.4 CNA hours requirement. The patient needs waiver for staff-to-patient ratios should already exist within the Department because the Department has already created a regulation establishing the patient needs waiver in title 22, California Code of Regulations, section 72329.1, subdivision (j). The Department should update this current waiver process as needed to reflect the changed requirements in statute and should delete the provision on the patient needs waiver from the proposed regulations.

Commenter(s): CANHR, LTCO

Response: No change was made in response to these comments. Though the patient needs waiver is authorized in a subdivision referencing development of staff-to-patient ratios, the Legislature did not intend to eliminate that waiver when it eliminated the ratios. SB 97 did not amend the first sentence of section 1276.65, subdivision (c)(2), which directs the Department to develop staff-to-patient ratios by converting the old 3.2 NHPPD standard under Health and Safety Code section 1276.5 and Welfare and Institutions Code section 14110.7. Because SB 97 replaced the 3.2 NHPPD standard, this sentence is superseded. However, SB 97 did amend the last sentence of subdivision (c)(2), which authorizes the patient acuity waiver, to reference the “3.5 direct care service hours per patient day required pursuant to subparagraph (B) of paragraph (1).” (§ 1276.65, subd. (c)(2).) These amendments indicate legislative intent that the patient acuity waiver should continue under the new 3.5 DCSHPPD requirement.

Comment: The patient needs waiver process should only allow for the substitution of additional licensed nursing care to offset any decrease in the need for less skilled care provided by CNAs. A waiver that would only reduce the hours of CNAs without a corresponding increase in licensed nursing care would undermine the statutory mandate to maximize resident quality of care.

Commenter(s): CNA/NNA

Response: No change was made in response to these comments. The Department agrees with the concerns identified by the commenter but believes the regulations include sufficient safeguards and account for these concerns. Subdivision (b)(1)(A)(iii) requires applicants for a patient needs waiver to submit information about the level of direct caregiver staffing the facility will provide if granted a waiver, including the number and type of staff. Further, the regulations permit the Department to revoke a patient needs waiver at any time if the facility is not complying with the terms and conditions under which the waiver was granted if the Department determines that the non-compliance poses a risk to the health, safety, or welfare of patients.

Comment: Requiring nurses to perform duties that are much more appropriately and efficiently provided by nursing assistants will lead to unintended consequences by resulting in negative patient outcomes. Nursing assistants provide vital daily care, including performing the activities of daily living (ADLs), while licensed nurses are providing medications and more complex treatments. Licensed nurses may be licensed to do it all, but they cannot do it all safely when they are required to do double duty. Employers requiring nurses to provide this additional care on top of their already strained workload are putting their patients' care and safety at risk.

Commenter(s): SEIU/NAC

Response: No change was made in response to these comments. This comment does not request a change to the regulations. Further, the regulations do not require facilities to substitute licensed nurses for CNAs. The purpose of the patient needs waiver is to permit facilities to use more licensed nurses when the facility demonstrates that its patients need more complex care that CNAs cannot provide. The waiver is an exception to the rule, and it is not intended to replace CNAs in the average SNF. Moreover, even if a facility receives a patient needs waiver, it is still required to staff at a minimum total of 3.5 DCSHPPD.

Comment: The Department's decision to require SNFs to submit information on their resident care needs is an improvement over the current program flexibility process.

Commenter(s): CNA/NNA

Response: The Department thanks the commenter for their comment.

Comment: SEIU agrees with the four types of substantiating information that a facility must submit as part of a patient needs waiver.

Commenter(s): SEIU

Response: The Department thanks the commenter for their comment.

Comment: A commenter expresses concern about possible gamesmanship involved in Minimum Data Set (MDS) scoring around Activities of Daily Living (ADL) assessment of SNFs that are reimbursed based on the MDS quality indicator. Attempts by SNFs to benefit financially by exaggerating the dependence of its resident population could undermine a patient needs waiver request. An artificial decline in resident ADLs would not benefit a facility applying for a waiver since CNAs provide the bulk of ADL care.

Commenter(s): CNA/NNA

Response: No change was made in response to these comments. As the commenter notes, if a facility attempted to benefit financially from exaggerating the level of dependence of its patients with respect to ADLs, the facility would undermine its request for a patient needs waiver.

Comment: SNFs applying for a patient needs waiver should be required to submit the most recent patient assessment for each resident. This requirement would not create any additional work for SNFs since they are already required to compile this information, and it would allow the Department to more accurately assess the facility's plan for the care of its residents under a waiver application.

Commenter(s): CNA/NNA

Response: No change was made in response to these comments. The application requirements in the regulations are sufficient to accurately illustrate the resident population and needs. Individual resident assessments would not provide additional benefit sufficient to justify adding this requirement to the waiver application process. Even if the requirement would not create additional work for SNFs, it would drastically slow the Department's review time for waiver applications without adding a proportionate increase in the probative value of the material, as resident assessments may change on a daily basis.

Comment: There is no explanation as to whether the entire subdivisions of (b)(2)(A) - (D) refer to the criteria that the Department will consider in reviewing waiver applications.

Commenter(s): SEIU

Response: When evaluating patient needs waiver applications, the Department will consider each of the items in subdivision (b)(2)(A) - (D) of the regulations. Subdivision (b)(2) of the regulation reads, "When evaluating waiver requests, the Department shall consider..." before listing the four criteria in (A) – (D).

Comment: There is no explanation as to what "compliance history" includes in subdivision (b)(2)(C). It is important to put measures in place to prevent facilities with a history of poor quality care from obtaining a waiver that would further affect their ability to provide optimal care for residents. A facility should be prohibited from applying for, or receiving, a patient needs waiver if they have received certain state and/or federal-level citations or deficiencies, including:

- State citations at the A or AA level in the last five years.
- Facilities that have had their license revoked or suspended.

- Federal deficiencies at levels 3 and 4 that include harm to resident health or safety.
- Failure to comply with “the 3.2 hprd regulations in place since 2000.”
- If the facility has received complaints and/or citations related to staffing levels and their impact on quality of care received at the facility.

Commenter(s): SEIU

Response: No change was made in response to these comments. Consideration of a facility’s “compliance history” is broad and would include all of the items recommended by the commenter. Stakeholders requested flexibility in assessment of patient needs waiver applications, so the Department did not create a list of specific acts of noncompliance that would automatically preclude a facility from receiving a patient needs waiver. However, the Department will consider all information related to a facility’s compliance with applicable state and federal law.

Comment: There is a lack of guidelines on things that may prohibit facilities from applying for, obtaining, and retaining a waiver. The regulations do not include information on the monitoring of facilities that the Department has granted a waiver. It seems that beyond the annual reassessment, there is an absence of accountability mechanisms for SNFs during the period in which they have an active waiver. The Department should reevaluate the ability of SNFs to retain waivers when they may be violating the terms of the waiver.

Commenter(s): SEIU

Response: No change was made in response to these comments. Stakeholder input indicated a desire for flexibility in the waiver application evaluation process, rather than a prescriptive approach, to account for the unique circumstances at each facility. As such, the regulations do not prohibit a facility from applying for or obtaining a waiver based on any enumerated criteria. However, each waiver application will be evaluated on a case-by-case basis, and the facility must at a minimum show that the patient needs at the facility warrant a waiver of the requirement to staff at 2.4 CNA hours per patient day. The Department already has a variety of monitoring and enforcement tools at its disposal, which serve as accountability mechanisms for SNFs. For example, the Department conducts annual recertification surveys, periodic licensing surveys, investigates complaints, and conducts annual staffing audits. Additionally, the Department amended the regulations following the 45-day public notice period to improve clarity around when the Department may revoke a patient needs waiver. The amended regulation provides that the Department may revoke approval of a waiver for non-compliance with the terms and conditions of the waiver, if the Department determines that the non-compliance poses a risk to the health, safety, or welfare of patients. This amendment may address some of the commenter’s concerns.

Comment: The Department should establish a timeframe within which the Department will approve or deny a waiver application. Not knowing if or when a waiver is going to be approved puts facilities in a tough situation.

Commenter(s): LA

Response: No change was made in response to these comments. While the Department has not established a timeframe for waiver processing, the Department intends to approve or deny waiver applications in a timely manner. The Department welcomes continued communication with stakeholders regarding this process.

Comment: The Department should post the waiver applications.

Commenter(s): CANHR

Response: No change was made in response to these comments. The Department is not contemplating posting waiver applications at this time. Even so, the posting of waiver applications is not suitable for regulation because it does not impose a regulatory requirement.

Comment: Changes to Medicare Part A that become effective October 1, 2018, will require greater numbers of licensed nurses. The new Patient Driven Payment Model will create the need for more intense assessments by licensed nurses, which will put greater financial pressure on facilities to meet staffing requirements. CAHF urges more flexibility for the Department to grant patient needs waivers when higher levels of better trained staff are present at facilities. CAHF asserts that CNAs are not necessarily the direct care service workers that typically drive quality outcomes in SNFs.

Commenter(s): CAHF

Response: No change was made in response to these comments. This comment does not request a specific change to the regulations. The proposed regulations provide the Department with the flexibility to evaluate all relevant factors when reviewing a waiver application, including the needs of residents, how the facility proposes to meet resident needs, and quality of care.

Comment: A financial penalty should be assessed on facilities that violate the terms of their waiver to ensure compliance.

Commenter(s): SEIU

Response: No change was made in response to these comments. The Department does not have the statutory authority necessary to assess a financial penalty on facilities that violate the terms of their waiver. The regulations permit the Department to revoke approval of a patient needs waiver at any time if the facility does not comply with the terms and conditions of the waiver and if the Department determines the non-compliance poses a risk to the health, safety or welfare of patients. The Department believes this is sufficient. In addition, standard penalties for citations would still apply in these facilities.

Comment: A commenter supports the requirement that a facility with a patient needs waiver notify the Department within 15 days of a change in certain substantiating information.

Commenter(s): SEIU

Response: The Department thanks the commenter for their comment.

Comment: The Department should impose a limit on the number of renewals a SNF may seek because the patient needs waiver should not be a permanent fixture at any SNF. The facility should submit a detailed resident care plan for those residents requiring a higher level of care with an anticipated date of recovery, discharge, or date by which the resident is expected to return to a state that would not require a higher ratio of licensed nurses to CNAs. The SNF should be required to immediately update the Department as soon as the conditions of their resident(s) changes and they no longer have higher acuity needs.

Commenter(s): SEIU

Response: No change was made in response to these comments. The Department holds facilities accountable for meeting the needs of its patients. If the patient needs at the facility continue to warrant a waiver because the facility continues to care for a higher acuity population, the Department sees no justification for discontinuing the waiver, so long as the facility is otherwise complying with the terms of the waiver. Further, the regulations provide for timely notification to the Department if the patients no longer have higher acuity needs. Subdivision (b)(3) requires a facility to notify the Department within 15 days if there is a change in the substantiating information submitted pursuant to subdivisions (b)(1)(A)(iv) or (b)(1)(B)(i). This means that for non-subacute care units, the facility must submit any change in the analysis of the resident needs at the facility within 15 days. The notification allows the Department an opportunity to reassess whether the waiver is still warranted.

Comment: Patient needs waivers should last one year, should not be revoked, and should not have a maximum number of renewals. The Department should not limit the number of patient needs waivers granted. A facility should not be penalized for having more licensed and qualified staff on the floor. Patient census and mix can change monthly, weekly, or even daily, and a licensed nurse can do everything a CNA does. Because of this, the commenter agrees with an annual renewal of waivers. Once a waiver is granted, it should not be revoked. When it is time for a waiver renewal, the Department can factor in information over that past year. So long as overall quality of care continues to be delivered and the facility remains above 3.5 overall DCSHPPD, the waiver should be granted. The Department should not apply the denial or revocation criteria for the workforce shortage waiver to the patient needs waiver.

Commenter(s): CAHF

Response: No change was made in response to these comments. Under the regulations, patient needs waivers last for one year, and there is no limit on renewals for the reasons stated above. Waivers will not be renewed if the facility can no longer demonstrate that a waiver is warranted, and waivers are only revoked if the facility does not comply with the terms of the waiver and the Department determines that the non-compliance poses a risk to the health, safety, or welfare of patients, which is reasonable to ensure resident safety and to uphold the legislative intent behind the waiver. The regulations do not apply the denial or revocation criteria for the workforce shortage waiver to the patient needs waiver, with the exception that in all instances the Department considers the compliance history of the facility, and the Department may revoke either waiver for non-compliance with the terms of the waiver. These criteria are

consistent with the Department's overarching responsibility to ensure patient safety. Additionally, the Department amended the regulations following the 45-day public notice period to improve clarity around when the Department may revoke a patient needs waiver. This amendment may address some of the commenter's concerns.

Comment: It would be unreasonable to impose a baseline requirement for obtaining a patient needs waiver that the majority of a facility's residents have documented higher acuity needs that require a higher ratio of licensed nurses to CNAs.

Commenter(s): CAHF

Response: This comment is non-responsive. The regulations do not impose such a requirement.

Comment: The Department received a number of comments regarding application of the patient needs waiver to subacute care units.

SEIU commented that subacute facilities, or subacute units within a SNF, should not be eligible to apply for a patient needs waiver as they are already staffing below 2.4 CNA hours. SEIU expressed concern that applying the patient needs waiver to a subacute care unit interferes with existing staffing regulations for subacute care units and allows those facilities to access a waiver that is not intended for them.

CAHF commented that subacute facilities, and facilities with subacute care units, should be granted an automatic patient needs waiver as long as they have a valid contract with DHCS and have passed their annual subacute staffing audit. CAHF would prefer SNFs with subacute units to have facility-wide waivers, but it states that if the waiver is limited to the subacute unit, it should be automatic. CAHF recommends limiting the provisions of subdivision (b)(2) to only SNFs without a subacute contract. CAHF expresses concern that the DHCS staffing requirements already applicable to subacute units are in direct conflict with the 3.5 and 2.4 requirements and can only be reconciled by automatic waivers.

CNA/HHA expressed concern that a rubber stamp waiver for any subacute unit would rob residents of the increase CNA hours required of all SNFs in SB 97 and would undermine the mandate to maximize resident quality of care.

Commenter(s): SEIU, CAHF, CNA/NNA

Response: No change was made in response to these comments. These comments indicate that there may be general confusion about how the 3.5 and 2.4 requirements apply to subacute care units. The new staffing requirements established in section 1276.65 are licensing requirements that apply to an entire SNF, including all of the units within the SNF, unless a specific statutory exemption applies. A subacute care unit is not a separate license type; it is an approved unit within a licensed SNF. Subacute care units may be only a wing or floor of a larger SNF, or the entire SNF may be approved as a subacute care unit. Even if the entire building is approved as a subacute care unit, the facility is still a SNF, and SNF licensing requirements apply. Because the minimum

CNA staffing requirements apply to a SNF, they apply to the facility as a whole, including a subacute care unit.

The patient needs waiver does not waive the 2.0 CNA hours requirement for subacute care units established and enforced by DHCS. As applied to a subacute care unit, the patient needs waiver permits the facility to continue staffing the subacute care unit at 2.0 CNA hours, and barring any other approved waiver, ensures the non-subacute portion of the facility still staffs at 2.4 CNA hours.

The simplified process for a subacute care unit to apply for a patient needs waiver helps ensure that the staffing requirements for subacute care units established by DHCS are not compromised or frustrated by these regulations.

Comment: A commenter identified minor errors in the use of nursing care terminology in the ISOR, page 4, and proposes the following modifications: “These patients are medically fragile and require special services, such as inhalation therapy, ~~tracheotomy~~ tracheostomy care, intravenous ~~tube~~-feeding, tube feeding, and complex wound management care.”

Commenter(s): CNA/NNA

Response: The Department accepted these changes and made minor non-substantial revisions to the ISOR to reflect more appropriate terminology.

Comment: The patient needs waiver should be phased out by 2019-2020.

Commenter(s): SEIU

Response: No change was made in response to these comments. The statute authorizing the patient needs waiver does not authorize a phasing out of the waiver. Establishing a sunset date would exceed the scope of the Department’s authority.

Comment: A commenter expresses concern that the SNFs applying for a patient needs waiver tend to have higher staff turnover rates than those that did not apply for a waiver. Facilities with unfavorable working conditions and lower quality of care are the ones benefitting from the patient needs waiver while still receiving the add-on payment. The Department should review the data on the facilities that applied for waivers and consider the impact on workers and residents.

Commenter(s): SEIU

Response: No change was made in response to these comments. The regulations require the Department to consider four (4) broad types of information when evaluating waiver requests, including resident quality of care and compliance history. The purpose of these criteria is to ensure that the Department looks at the facility as a whole and considers the impact that a waiver might have on the facility and residents.

Comment: Concern about the punitive nature of the regulation, even with the delay in implementation of the penalties.

Commenter(s): LA

Response: No change was made in response to these comments. This comment does not request a specific change to the regulations.

5. COMMENT SUBJECT: WORKFORCE SHORTAGE AND WORKFORCE SHORTAGE WAIVER

Comment: The Department should continue to allow communities to apply for program flexibility related to the 3.5 DCSHPPD and 2.4 CNA hours per patient day requirements until there are enough CNAs in the state and in local communities to meet the requirements. One commenter states that it has been unable to sustain minimum staffing on some days of the week or month, despite having a robust incentive program, a progressive disciplinary program, an in-house CNA training class, and spending “thousands of dollars a month in recruitment” in the local area. The commenter attributes this in part to the high cost of housing, a semi-rural population to recruit from, and competition from other health facilities and home care agencies in the area. Another commenter notes that it has “been very difficult to find and locate properly prepared staff for the 3.5 regulatory requirement.”

Commenter(s): GCRC, RHF1, RHF2, ARCT

Response: No change was made in response to these comments. Because these commenters describe an inability to hire and retain qualified CNAs, the Department presumes that these commenters are referring to the workforce shortage waiver, which is available to address a shortage of available and appropriate health care professionals and direct caregivers. The Department implemented the workforce shortage waiver through an AFL, as authorized by section 1276.65, subdivision (I); that waiver has never been available using the program flexibility process. The only waiver that was previously implemented using the program flexibility process was the patient needs waiver, which permitted facilities to request a waiver of the 2.4 CNA hours requirement based on the specific needs of residents at the facility. Because the Department has implemented the workforce shortage waiver via its AFL authority, the Department declines to adopt overlapping provisions in these regulations. Facilities facing a shortage of available and appropriate direct caregivers may apply for a workforce shortage waiver.

Comment: Implementation of the workforce shortage via AFL violates the California Administrative Procedure Act.

Commenter(s): CAHF

Response: Subdivision (c)(1) of the regulations directs a facility to submit a written request for a workforce shortage waiver pursuant to the AFL issued by the Department. This language is only included to improve clarity for the regulated community and simply references the AFL authority provided by SB 97. SB 97 directs the Department to create a waiver of the direct care service hour requirements to address a shortage of available and appropriate health care professionals and direct caregivers. (§ 1276.65, subd. (I).) The statute authorizes the Department to create this waiver via AFL, which it has done. (§ 1276.65, subd. (I).) The Department references this waiver and the associated AFL in the proposed regulations solely to improve clarity and reduce

confusion for the regulated community by indicating where the regulated community can find the criteria for applying for a workforce shortage waiver.

Comment: The Department should narrow the workforce shortage waiver adopted in AFL 18-16.

Commenter(s): CANHR

Response: No change was made in response to these comments. These regulations do not include criteria for the workforce shortage waiver. All requirements related to that waiver are addressed in AFL 18-16.

Comment: The Department should post the waiver applications.

Commenter(s): CANHR

Response: As it relates to the posting of workforce shortage waiver applications, this comment is non-responsive. All requirements related to that waiver are addressed in AFL 18-16.

6. COMMENT SUBJECT: SMALL HOUSE SNFS

Comment: A commenter is concerned that the regulations do not adequately address some of the emerging small house SNF concepts that have been proposed. Facilities would like to participate in that program, but they feel there is a lack of clarity around how small house SNF staffing would be defined in that community. They would like more clarity around whether this is addressed in these regulations or in another venue.

Commenter(s): LA

Response: No change was made in response to these comments. The Small House SNF Pilot Program Standards, as published on the Department's website, address the state and federal law applicable to participating SNFs, including staffing requirements. Pursuant to these standards, all provisions of the Health and Safety Code and title 22 of the California Code of Regulations pertaining to SNFs apply to all pilot facilities, except as modified or supplemented by the Department in the standards or in any subsequent AFL pertaining to small house SNFs, or subject to a waiver under section 1323.5, subdivision (k). SNFs participating in the pilot program may apply for waivers as part of their pilot application.

7. COMMENT SUBJECT: REQUEST FOR INCREASED MEDI-CAL REIMBURSEMENT

Comment: Three commenters request an increase in Medi-Cal reimbursement to pay for the increased staffing requirements and rising minimum wage, and the cost of training internally.

Commenter(s): GCRC, RHF1, RHF2

Response: This comment is non-responsive and outside the scope of the regulations. The requested activity is also outside the scope of the Department's authority. The Department of Health Care Services administers the Medi-Cal program; the Department cannot increase Medi-Cal reimbursement rates.

8. COMMENT SUBJECT: REQUEST FOR FUNDING TO INCREASE NUMBER OF CNAs AND CNA TRAINING PROGRAMS

Comment: The Department should expand funding and advertising to encourage CNA training programs within the state and to provide “funding for SNF communities CNA training programs to increase the number of CNAs.”

Commenter(s): GCRC, RHF1, RHF2

Response: This comment is not directed at the proposed regulations and requests funding that requires a budgetary allocation. The State has taken the following actions in recognition of the need to expand CNA training options:

- The 2018 Budget provides Community Colleges with one-time funding of \$2 million to expand CNA training.
- CDPH awarded a \$2.4 million state grant to the California Association of Health Facilities’ (CAHF) non-profit education foundation to increase the number of in-house CNA training programs.
- The Employment Training Panel (ETP) awarded \$2.5 million to reimburse training providers for CNA training.
- Effective January 1, 2019, AB 2850 (Chapter 769, Statutes of 2018) authorizes CNA precertification training programs offered by skilled nursing facilities (SNF), intermediate care facilities (ICF), local agencies, and educational institutions to seek approval from CDPH to offer the required 60 classroom hours of CNA precertification training through online or distance learning courses.

9. COMMENT SUBJECT: REQUEST TO IMPOSE BAN ON ADMISSIONS FOR UNDERSTAFFED FACILITIES

Comment: The Department should impose a ban on admissions for understaffed nursing homes.

Commenter(s): CANHR

Response: No change was made in response to these comments. Stakeholders previously raised the issue of imposing a ban on admissions for facilities seeking waivers. The Department elected not to include this option because imposing a ban on admissions would limit access to care. The Department has an array of enforcement tools it can use when a facility fails to meet the needs of patients including the issuance of a citation or other enforcement action. A ban on admissions is a serious remedy reserved for serious violations. Removing beds from the community would only exacerbate existing bed shortages in many areas and may not serve the best interests of patients.

10. COMMENT SUBJECT: CONCERNS ABOUT PENALTIES FOR NONCOMPLIANCE

Comment: Three commenters requested that the Department remove the State's fines for staffing at levels that are higher than the community can find staff for.

Commenter(s): GCRC, RHF1, RHF2

Response: No change was made in response to these comments. This requested change is outside the scope of the Department's authority. The Department cannot waive the administrative penalties established by the Legislature for failure to comply with the staffing requirements in sections 1276.5 and 1276.65, as applicable. The Department has already implemented a phase-in of penalties to give facilities time to come into compliance with the new requirements. Again, facilities that cannot meet the minimum staffing requirements due to a workforce shortage may apply for a workforce shortage waiver.

11. COMMENT SUBJECT: CONCERN THAT REGULATIONS DO NOT SERVE THEIR STATED PURPOSE AND WOULD HARM RESIDENTS' ABILITY TO RECEIVE CARE

Comment: The regulations "do not serve their stated purpose to align the Department's regulations with changes to statute" and would "harm nursing home residents' ability to receive needed care." The "Department's excessive focus on waiving California's minimum staffing requirements is harming residents' ability to receive needed care." A commenter expresses concern that by processing waiver applications, the Department has been put in "the perverse role of endorsing understaffing at California's most poorly staffed nursing homes." This commenter is concerned that this role undermines the Department's enforcement mission and gives the public the impression that the Department is serving nursing home owners, not them.

Commenter(s): CANHR

Response: No change was made in response to these comments. This comment does not request a specific change to the regulations. The Department has developed regulations that comply with the legislative mandate to implement the changes made by SB 97.

12. COMMENT SUBJECT: CONCERN ABOUT NO REASONABLE ALTERNATIVES DETERMINATION

Comment: In the ISOR, the Department claims no one has brought any reasonable alternatives to its attention.

Commenter(s): CANHR

Response: The Department did not make any such claim. The ISOR states:

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.

The Department considered all of the suggestions submitted by stakeholders in-person during the stakeholder meetings as well as the written recommendations submitted since the passage of SB 97. While the Department considered all suggestions, it did not adopt all stakeholder recommendations.

13. COMMENT SUBJECT: CONCERN ABOUT CONSISTENCY AND COMPATIBILITY WITH STATE REGULATIONS DETERMINATION

Comment: A commenter disagrees with the Department's assertion in the Notice of Proposed Rulemaking that "no known statute or operative regulation conflicts with this regulatory action." This commenter expresses concern that the proposed regulations do not address California Code of Regulations, title 22, section 72329.1, and urges the Department to amend that regulation to conform it to statutory changes increasing the minimum staffing requirement. This commenter recommends that the Department adjust the ratios in California Code of Regulations, title 22, section 72329.1 upward to reflect the new 3.5 DCSHPPD requirement.

Commenter(s): CANHR

Response: No change was made in response to these comments. The regulations in California Code of Regulations, title 22, section 72329.1, were promulgated under the previous version of section 1276.65. SB 97 and the regulations promulgated pursuant to the amended section 1276.65 supersede the previous regulations.

14. COMMENT SUBJECT: CONCERN ABOUT LACK OF LEGISLATIVE HISTORY

Comment: There is no legislative history on SB 97 and that the minimum staffing provisions are "shrouded in mystery." During the stakeholder meetings on SB 97, the Department was unable to produce any legislative history. In response to its Public Records Act request on this subject, the Department responded stating that it had no documents or records that could be shared.

Commenter(s): CANHR

Response: These comments are non-responsive. This comment does not request a modification to the text and is not directed at the proposed regulations.

15. COMMENT SUBJECT: CONCERN ABOUT INADEQUATE STAKEHOLDER ENGAGEMENT

Comment: The Department has not engaged in meaningful discussions with stakeholders on the adequacy of the minimum staffing requirements. The Department should meet with stakeholders, consider the adequacy of the SNF staffing requirements, and set standards that ensure high quality care for residents.

Commenter(s): CANHR

Response: The Department has complied with all requirements to engage stakeholders in the implementation of SB 97, including the requirement in section 1276.65, subdivision (c)(1)(D), to consult with stakeholders prior to promulgation of the regulations. The Department conducted extensive stakeholder engagement during the development of both the emergency and permanent regulations. This included three in-person stakeholder meetings between November 2017 and March 2018 and two in-person stakeholder meetings in July 2018. The Department also invited stakeholders to submit written comments on numerous occasions between August 2017 and July 2018. The Department solicited and welcomed input on all aspects of SB 97 implementation, including the 3.5 DCSHPPD staffing requirement. Stakeholders had the opportunity to raise concerns about the adequacy of the minimum requirements established by the Legislature. The Department created a webpage related to implementation of SB 97, where it posted meeting minutes, pre-notice written submitted comments, documents related to implementation such as AFLs and lists of waiver applicants, and information on how to submit additional comments and questions.

As required by section 1276.65, subdivision (m), the Department will evaluate the impact of the new minimum staffing requirements regarding resident quality of care, workforce availability, and effectiveness of the requirements.

Comment: The Department has never taken seriously its duty to meet with stakeholders under section 1276.65, subdivision (e):

No later than January 1, 2006, and every five years thereafter, the department shall consult with consumers, consumer advocates, recognized collective bargaining agents, and providers to determine the sufficiency of the staffing standards provided in this section and may adopt regulations to increase the minimum staffing ratios to adequate levels.

Commenter(s): CANHR

Response: This comment does not request a modification to the text and is not directed at the proposed regulations.

16. COMMENT SUBJECT: REQUEST TO UPDATE CONTACT INFORMATION

Comment: CASE requested that the Department send all future correspondence for CASE to the attention of Katherine E. Regan. The Department received this comment after the close of the public comment period.

Commenter(s): CASE

Response: This comment does not request a modification to the text and is not directed at the proposed regulations.

ADDENDUM II
15-Day Public Notice
Summary of Comments and Responses to Comments Received

The Department received comments from one (1) commenter during the 15-day public notice period beginning December 18, 2018, and ending January 2, 2019. The comments below are aggregated and summarized or are responded to individually.

LIST OF COMMENTERS (WT – Written Testimony, VT – Verbal Testimony)

1. Private Citizen, Sandra J. Haskins WT

1. COMMENT SUBJECT: CONCERN ABOUT WORKFORCE SHORTAGE AND RETAINING QUALIFIED STAFF

Comment: The new staffing requirements are an attempt to force staff to perform without mistake and come to work as scheduled, neither of which can be achieved through staffing requirements. The Department cannot regulate perfection. Instead of trying to regulate success and safety, the Department should help facilities solve the staffing crisis in the community. The inability to staff consistently at the higher minimum requirements is directly linked to the number of qualified individuals in the community that can enter a training class as well as their level of dedication to their career. I have done everything to recruit, raise pay, offer bonuses, and more, and still cannot increase the roster. I am not alone in my angst over recruiting and retaining qualified staff, especially CNAs. Restricting admissions because facilities cannot meet minimum staffing requirements will not help California seniors and will impact hospitals.

Commenter(s): Ms. Haskins

Response: No change was made in response to these comments. These comments are non-responsive and outside the scope of the proposed regulation text included in the 15-day notice of public availability. The Department has developed regulations that comply with the legislative mandate to implement the minimum staffing requirements established by SB 97. Facilities facing a shortage of available and appropriate direct caregivers may apply for a workforce shortage waiver. The State has also taken several actions to support expansion of CNA training options, as referenced above.

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. The only alternatives presented to or otherwise identified by the Department are those discussed and responded to in the summary and response to comments.

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.

STATEMENT OF GOOD CAUSE FOR EARLIER EFFECTIVE DATE

The Department requests that the proposed regulations become effective upon filing with the Secretary of State to avoid confusion for facilities and potential harm to residents. The proposed regulations require facilities to submit a request for a patient needs waiver annually by April 1 of each year and set out specific criteria for waiver applications. This waiver permits a facility to waive the requirement to provide a minimum of 2.4 CNA hours per patient day based on the unique needs of residents at that facility. Whether a facility has a waiver impacts the staffing mix at a facility as well as DHCS reimbursement rates. To provide facilities sufficient time to prepare a waiver and submit timely applications pursuant to the proposed regulatory requirements, the regulations must become effective before April 1.