

FINAL STATEMENT OF REASONS FOR PROPOSED CHANGES TO
THE CALIFORNIA CODE OF REGULATIONS, TITLE 22, DIVISION 7,
CHAPTER 10, HEALTH FACILITY DATA

ARTICLE 8: PATIENT DATA REPORTING REQUIREMENTS

97240. Request for Modifications to Patient Data Reporting.

As required by Health and Safety Code Section 128760, the Office many years ago adopted a regulation that specifies how hospitals and ambulatory surgery facilities that report patient level-data may request modifications to the reporting requirements. The Office is now updating that regulation, Section 97240 of Title 22.

TEXT

(a) Reporting facilities may file a request with the Office for modifications to Hospital Discharge Abstract Data, Emergency Care Data, or Ambulatory Surgery Data reporting requirements. The modification request shall be supported by a detailed justification of the hardship that full reporting of data would have on the reporting facility; an explanation of attempts to meet data reporting requirements; and a description of any other factors that might justify a modification. Modifications may be approved for no more than one year. ~~Each reporting facility with an approved modification must request a renewal of that approval 60 days prior to termination of the approval period in order to have the modification continue in force.~~

THE PROBLEM TO BE ADDRESSED AND THE RATIONALE FOR AMENDMENT

The requirement to request a renewal of a modification approval 60 days prior to the termination of the approval period is no longer necessary. Modifications are now processed in an online environment rather than a hardcopy postal service mail environment. The need to allow for repeated postal service mailing time for hardcopy reports and letters has been eliminated by the ability to view reports on a computer screen simultaneously at OSHPD and in the facility requesting the modification, and the ability to use electronic messaging capabilities to communicate requests in written form.

THE BENEFIT TO BE REALIZED

The elimination of a specific time to request a modification allows facilities greater convenience. They may choose to initiate a modification request at any time, at their convenience, without being held to an obsolete timeframe. The request for modification process will be more user-friendly for facilities who will initiate requests at their own convenience. This will make for more efficient processing at OSHPD because requests for modifications will arrive on a more gradual basis rather than all at once, 60 days before a termination of approval date.

REASONABLE ALTERNATIVES

No alternatives that are more reasonable than allowing facilities to choose the timing of a request have been developed by OSHPD. We conducted a 45 day public comment period

and were open to the consideration of any reasonable alternatives that might better meet the needs of reporting facilities; no alternatives were proposed.

PUBLIC COMMENT

There were no comments recommending any modification to this proposed text deletion; the text will be deleted.

TEXT

Modifications to the data reporting requirements must be approved before data to which they apply will be accepted.

THE PROBLEM TO BE ADDRESSED AND THE RATIONALE FOR AMENDMENT

When data is submitted to OSHPD online it is subjected to automated editing programming. Data will not be accepted if it does not meet the requirements. When a facility determines that its data is failing, despite their serious documented correction efforts, then they may request a modification. Requesting a modification prompts OSHPD to consider the specific facility justification and hardship and consider modifying the requirement that is preventing the acceptance of the data set. The added text, then, is a reminder that a request must be made before modified data can be approved. It is a statement of practicality that OSHPD has determined could benefit facilities.

THE BENEFIT TO BE REALIZED

Modifications have to be requested by a facility, they are not generated by OSHPD. It is hoped that this statement will bring clarity to the modification requesting process.

REASONABLE ALTERNATIVES

No alternatives that are more reasonable than allowing facilities to choose the timing of a request have been developed by OSHPD. We conducted a 45 day public comment period and were open to the consideration of any reasonable alternatives that might better meet the needs of reporting facilities; no alternatives were proposed.

PUBLIC COMMENT

There were no comments recommending any modification to this proposed text; the text will be included in the final text.

TEXT

~~(b) The criteria to be considered and weighed by the Office in determining whether a modification to data reporting requirements may be granted are as follows:~~

- ~~(1) The modification would not impair the ability of either providers or consumers to make informed health care decisions.~~
- ~~(2) The modification would not deprive the public of data needed to make comparative choices with respect to scope or type of services or to how services are provided, and with respect to the manner of payment.~~
- ~~(3) The modification would not impair any of the goals of the Act.~~

In determining whether a modification to data reporting requirements will be approved, the Office shall consider the information provided pursuant to subsection (a) and evaluate whether the requested modifications would impair the Office's ability to process the data or interfere with the purposes of the data reporting programs.

THE PROBLEM TO BE ADDRESSED AND THE RATIONALE FOR AMENDMENT

The text being deleted was not clear or easy to understand. The proposed text is intended to be easier to understand. There is no intention to change the criteria for approving a modification.

A criticism can be raised that both the former text and the new proposed text are subjective, that the criteria are not precisely defined. This is due to the complexity of the issues involved in determining whether OSHPD can or cannot accept modified data. Each modification request is specific to the requesting facility, supported by a detailed justification of the hardship that full reporting of data would have on the reporting facility, an explanation of attempts to meet data reporting requirements, and a description of any other factors that might justify a modification. OSHPD is committed to collecting and reporting the most accurate data that it can collect. Regulations specify what must be reported, and how it must be reported, for each data element (Sections 97210 - 97267). With two data sets (Inpatient and Outpatient), composed of three types of Data Record (Hospital Discharge Data, Emergency Care Data Record, Ambulatory Surgery Data Record), and approximately 20 data elements in each data set, it has not proved to be practical to write regulations specific to every potentially allowable modified combination of data elements and circumstances that might allow OSHPD to accept a modified data set. Modifications have, of necessity, since the first request was made, been considered on a case by case basis.

THE BENEFIT TO BE REALIZED

The benefit to the new language is that it indicates that the Office will apply the criteria listed in the statute in making determinations.

REASONABLE ALTERNATIVES

No alternatives that are more reasonable than requiring a facility to provide a detailed justification of the hardship that full reporting of data would have on the reporting facility; an explanation of attempts to meet data reporting requirements; and a description of any other factors that might justify a modification, that meets the requirement of the statute has been developed by OSHPD. We conducted a 45 day public comment period and considered reasonable the reasonable alternative of not updating the text, as recommended by a commenter but determined that the proposed text would better meet the needs of facilities and also fulfill the requirements of the statute.

PUBLIC COMMENT

We conducted a 45 day public comment period. The first sentence of OSHPD's proposed text was not felt, by the commenter, to be an improvement over the clarity of the current text. Also, it was perceived as a change in the criteria for approving a modification. There is no change in the criteria for approving a modification; the text makes it clear that we are

following the statutory criteria. We always consider the specific facility justification and hardship; the hardship is the basis for the facility making the request for a modification.

OSHPD considered the reasonable alternative of not updating the text, as recommended by a commenter, but believes that the proposed text could better meet the needs of facilities. The language was developed in response to facility questions made over a span of several report periods.

The revised language, it was suggested, shifts the focus away from the needs of the consumers and other data users. OSHPD does not agree; making good and useful data available to consumers and other data users is the purpose of the data reporting programs. The commenter suggested that the focus of the proposed text was away from facility hardship and toward the Office's ability to process the data. This suggestion is respectfully rejected because data is received and processed in an online environment. If a facility submits data in a format that is unreadable then that data cannot be processed and is not available to be added to the database. An incomplete database reduces the value of the data to its consumers; the focus on data processing is not only an internal priority, it is a vital concern because it has consequences for all data consumers. The interests of data consumers continue to be a priority for OSHPD.

TEXT

Any modifications to reporting requirements are subject to disclosure to data users.

THE PROBLEM TO BE ADDRESSED AND THE RATIONALE FOR AMENDMENT

This statement explicitly states that data users will see statements listing any modification. This has been OSHPD data user business practice for many years and is now being stated for data providers. OSHPD is obligated to inform users of any data that it has approved that do not fully meet stated regulatory requirements. Data users may then use the statements of modification to determine whether to include, or exclude, modified data in their analysis or project.

THE BENEFIT TO BE REALIZED

The benefit is not specifically quantifiable. The realization that their facility data is being labeled as "modified" may prompt facilities to remedy data deficiencies more promptly.

REASONABLE ALTERNATIVES

No alternatives that are more reasonable than allowing facilities to choose the timing of a request have been developed by OSHPD. We conducted a 45 day public comment period and were open to the consideration of any reasonable alternatives that might better meet the needs of reporting facilities; no alternatives were proposed.

PUBLIC COMMENT

There were no comments recommending any modification to this proposed text. The comment suggested placing this sentence in a new subsection (c). This suggestion was

considered; with the continued use of the current text in subsection (b) this added text is being relocated to become the last sentence in subsection (a) where it provides additional information appropriate to that subsection.

TEXT

No amendments were proposed for subsections (c) and (d).

ECONOMIC IMPACT ANALYSIS

There are no added costs or reduced costs as a result of this regulatory proposal. This amendment eliminates the specific 60 day filing requirement and restates the factors that will be considered. The request for modification process will be more user-friendly for facilities because they will initiate requests at their own convenience instead of on an obsolete timeframe. The amount of time, effort and resources required by a facility to make a request will not change.

If any economic impact results it may be positive in that a facility may make a request at time convenient to their ongoing workload; they may avoid employee overtime expenses. This potentially positive economic impact cannot be calculated with any accuracy.

Potentially the elimination of the 60 day timeframe may also allow more efficient processing at OSHPD because requests for modifications may arrive on a more gradual basis rather than all at once, 60 days before a termination of approval date. This potential economic impact cannot be accurately calculated but is estimated to be minor.

LOCAL AGENCIES/SCHOOLDISTRICTS MANDATE

Pursuant to Government Code 11346.9(a)(2) OSHPD has determined that this regulation affects only reporting entities (hospitals) who request modifications to patient data reporting requirements. Local agencies and school districts do not report any patient data to OSHPD and therefore this regulation imposes no mandate upon local agencies or school districts.

REASONABLE ALTERNATIVES

As already discussed in this Final Statement of Reasons section and pursuant to Government Code 11346.9(a)(4), no reasonable alternatives been developed by OSHPD or brought to OSHPD's attention. We conducted a 45 day public comment period and were open to the consideration of any reasonable alternatives that might better meet the needs of facilities however no alternatives were proposed or brought to OSHPD's attention that would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective and less burdensome to affected private persons than the adopted regulation, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. Data providers, rather than private persons, are affected by this regulation.

IDENTIFICATION OF ANY TECHNICAL, THEORETICAL, OR EMPIRICAL DOCUMENTS, STUDIES, REPORTS RELIED UPON IN PROPOSING THIS REGULATORY ACTION

There are no formal technical, theoretical or empirical documents, studies or reports relied upon in proposing this regulatory action. The basis for this proposed regulatory action is the practical observation that operating in an online data submission and processing environment, where data can be viewed and processed online, in very short time frames, there is no need to use hardcopy mailing services. With no need to accommodate the modification process workload around postal service delivery schedules, in-house document delivery services, and the elimination of the need to track and record hardcopy mailings, there is no longer any need for 60 days to ensure timely processing of modification. Thus, the proposal to eliminate the 60 day requirement arose.

FACTS, EVIDENCE, DOCUMENTS, ETC ON WHICH THE AGENCY RELIES UPON TO SUPPORT AN INITIAL DETERMINATION THAT THE ACTION WILL NOT HAVE A SIGNIFICANT ADVERSE IMPACT ON BUSINESS

These regulations only affect the subsection of hospitals who request modifications to patient data reporting requirements. There are only 10 Ambulatory Surgery Centers who meet the criteria for small businesses (11342.610)(a)(11) A healthcare facility having annual gross receipts of less than \$1,500,000). If these clinics do not initiate any requests to modify their data reporting they will not be affected.



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July 20, 2012

Ron Spingarn, Deputy Director
Healthcare Information Division
Office of Statewide Health Planning and Development (OSHPD)
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RE: Section 97240 Request for Modifications to Patient Data Reporting

Dear Deputy Director Spingarn:

The California Nurses Association (CNA) appreciates the opportunity to comment on the proposed changes to the Health and Safety Code related to facility requests for modifications to patient data reporting.

We understand that changes in the manner in which data is now being submitted no longer require that 60 days notice be given for renewal of an approved modification. The deletion of:

“Each reporting facility with an approved modification must request a renewal of that approval 60 days prior to termination of the approval period in order to have the modification continue in force”

is consistent with the stated purpose of updating the process in light of improved electronic messaging capabilities and the electronic filing of data by health facilities. The addition of language informing health facilities that “[m]odifications to the data reporting requirements must be approved before data to which they apply will be accepted” is clearly stated and we have no comments for modification to subsection (a).

The proposed changes to subsection (b) substitutes language that has been previously approved by the Office of Administrative Law and that met the substantive criteria of Necessity, Authority, Clarity, Consistency, Reference and Non-duplication with language that only paraphrases the statutory language already found in H&S Code Section 128760:

“(c) Modifications to discharge data reporting requirements. The office shall allow and provide, in accordance with appropriate regulations, for modifications to discharge data reporting format and frequency requirements *if these modifications will not impair the office’s ability to process the data or interfere with the purpose of this chapter.*” (Emphasis added)

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Ron Springarn
OSHPD
July 20, 2012
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The proposed new language:

“ In determining whether a modification to data reporting requirements will be approved, the Office shall consider the information provided pursuant to subsection (a) and evaluate whether the requested modification would impair the Office’s ability to process the data or interfere with the purposes of the data reporting programs”

is supposed to be easier to understand and purportedly makes no change in the criteria for approving a modification. CNA believes that this proposed language makes a change in the criteria for approving a modification. In addition, the proposed new language does not clarify or make specific the referenced statutory language which is one of the goals of rulemaking.

Currently the criteria to be considered and weighed by OSHPD includes that the modification:

- (1) would not impair the ability of either providers or consumers to make informed health care decisions;
- (2) would not deprive the public of data needed to make comparative choices with respect to scope or type of services or to how services are provided and with respect to the manner of payment; and
- (3) would not impair any of the goals of the Act.

The proposed regulatory language is being changed from a focus on the healthcare consumers and the public’s need for data when considering facility requests for modification based on a claim of hardship, to a focus on whether the Office is able to process the data. OSHPD notes that both the old language and the new language are subjective so there has been nothing gained in clarity by the substitution.

One of the earliest sections under the Health Data and Advisory Council Consolidation Act, H & S Code Section 128681 instructs OSHPD to conduct, under contract with a qualified consulting firm, a comprehensive review of the financial and utilization reports that hospitals are required to file. The legislature stated that the contracting firm, “...shall have a strong commitment to public health and health care issues, and shall demonstrate fiscal management and analytical expertise...”. While this section does not relate specifically to the rulemaking section or to the data under consideration, the fact that fiscal expertise was not the only consideration in the hiring of a consulting firm indicates the legislature’s interest in keeping public health and health care issues front and center. The section places the public’s health and welfare first in the order of qualifications and CNA believes that OSHPD too should place the interest of consumers clearly in the mix when considering modification approvals.

CNA requests that Section 97240 (b)(1), (2), and (3) remain unchanged and that the proposed new language, “ Any modifications to reporting requirements are subject to disclosure to data users” be added as a new subsection (c) with the subsequent subsections changed to (d) and (e). This new language would not make sense in subsection (b) since it is a list of criteria to be considered and weighed by OSHPD when considering requests for modification.

Ron Springarn
OSHDP
July 20, 2012
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Thank you for considering our comments on these proposed changes. The information gathered by OSHDP is critical to the evaluation of the quality of healthcare provided in California and we appreciate your ongoing contribution to transparency in collecting , evaluating and reporting healthcare data. If you have any questions regarding our comments, please contact me at the CNA office at 916-446-5019.

Sincerely,

A handwritten signature in black ink that reads "Bonnie Castillo". The signature is written in a cursive, flowing style.

Bonnie Castillo RN
Director of Government Relations

Ogbonna, Irene@OSHPD

From: Spingarn, Ron@OSHPD
Sent: Friday, July 20, 2012 9:47 AM
To: cboren@calnurses.org
Cc: Ogbonna, Irene@OSHPD
Subject: FW: CNA Comments - RE: Section 97240 Request for Modifications to Patient Data Reporting
Attachments: 20120720111839.pdf
Importance: High

Thank you for your comments. We have received them and will be replying at a later date.

Ron Spingarn
Deputy Director
Healthcare Information Division
California Office of Statewide Health Planning & Development
(916) 326-3801

From: Corinne Boren [<mailto:cboren@calnurses.org>]
Sent: Friday, July 20, 2012 9:20 AM
To: Spingarn, Ron@OSHPD
Subject: CNA Comments - RE: Section 97240 Request for Modifications to Patient Data Reporting
Importance: High

Dear Deputy Director Spingarn,

Here are CNA's comments regarding Section 97240.
Please let me know that they have been received.

Thank you, Corinne

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August 30, 2012

Bonnie Castillo, RN, Director of Government Relations
California Nurses Association
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Dear Ms. Castillo,

Thank you for your July 20 public comment and your interest in our regulatory proposal to amend Section 97240 of Title 22. The Office appreciates both your support for some of the proposed changes and your concern about others. OSHPD proposed the new language because a number of our data reporters found the repealed regulatory language confusing. OSHPD finds the proposed text to be simpler, clearer, and more consistent with the Statute.

Although we understand your concern that in modifying the language in Subdivision (b), we might shift the focus of our review, our intent in re-wording the criteria is to simplify the section and make it clear to facilities that we are following the statutory criteria. We don't agree that the revised language shifts the focus away from the needs of consumers and other data users; making good and useful data available to consumers and other data users is "the purposes of the data reporting programs."

Reference to the Office's ability to process the data is also in the statute and is an important factor. If the Medical Information Reporting for California (MIRCal) online system used to accept and edit incoming facility data cannot "read" a facility's data submitted we cannot process it; this results in no data. We share your opinion of the importance of the purposes of the Data Act and will continue to give consideration to the effect a modification might have on provision of data to the public, providers, and consumers. As an office that provides a wealth of healthcare data on our website, and customized data to researchers across a wide spectrum of public, private, and government healthcare interests, we consider the Office to be a responsible steward of public benefits.

Thank you for your suggestion that the sentence regarding disclosure of modifications would be more useful elsewhere. OSHPD has modified its proposed text by moving the proposed additional sentence "Any modifications to reporting requirements are subject to disclosure to data users." from (b) to (a).

We appreciate your comments and your concern for the consumers of healthcare data. We have always applied the statute and intent of the Act while carrying out our statutory authority in our role in collecting, evaluating, providing and reporting healthcare data.

Sincerely,

A handwritten signature in black ink that reads 'Ron Spingarn'.

Ron Spingarn
Deputy Director
Healthcare Information Division