GAVIN NEWSOM, GOVERNOR

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PROPOSED ACTION ON REGULATIONS

GENERAL PUBLIC INTEREST

(Continued on next page)

Time-Dated Material

SUMMARY OF REGULATORY ACTIONS

The *California Regulatory Notice Register* is an official state publication of the Office of Administrative Law containing notices of proposed regulatory actions by state regulatory agencies to adopt, amend or repeal regulations contained in the California Code of Regulations. The effective period of a notice of proposed regulatory action by a state agency in the *California Regulatory Notice Register* shall not exceed one year [Government Code § 11346.4(b)]. It is suggested, therefore, that issues of the *California Regulatory Notice Register* be retained for a minimum of 18 months.

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PROPOSED ACTION ON REGULATIONS

Information contained in this document is published as received from agencies and is not edited by Thomson Reuters.

TITLE 10. DEPARTMENT OF REAL ESTATE

CRITERIA FOR SUBSTANTIAL RELATIONSHIP — SECTIONS 2910 and 2910.5

NOTICE IS HEREBY GIVEN

The Commissioner ("Commissioner") of the Department of Real Estate ("DRE") proposes to amend Section 2910 and add Section 2910.5 to the Regulations of the Real Estate Commissioner (Title 10, Chapter 6 of the California Code of Regulations) ("the Regulations") after considering all comments, objections, and recommendations regarding the proposed action. Publication of this notice commences a 45−day public comment period.

PUBLIC HEARING

A public hearing is not scheduled. A public hearing will be held if any interested person, or that person's duly authorized representative, submits a written request for a public hearing to DRE at the contact listed below no later than 15 days prior to the close of the written comment period.

WRITTEN COMMENT PERIOD

Any interested person, or that person's authorized representative, may submit written comments relevant to the proposed regulatory action to the Commissioner addressed as follows:

Regular Mail

Department of Real Estate
Attn: Daniel E. Kehew, Sacramento Legal Office
P.O. Box 137007
Sacramento, CA 95813−7007

Electronic Mail

DRERegs@dre.ca.gov

Facsimile

(916) 263−8767

Comments may be submitted until 5:00 p.m., Tuesday, August 18, 2020.

AUTHORITY AND REFERENCE

Section 10080 of the Business and Professions Code ("the Code") authorizes the Commissioner to adopt regulations that are reasonably necessary for the enforcement of the provisions of the Real Estate Law (Code Sections 10000 et seq.). The proposed regulations implement, interpret, and make specific Sections 480, 481, and 490 of the Code.

The reference note for Section 2910 includes the California Supreme Court decision *In re Gossage* (2000) 23 Cal 4th 1080. That case addressed a licensing body's use of past criminal convictions to determine an applicant's fitness to practice. DRE relied on *In re Gossage* in its earlier development of the Section 2910. The case remains relevant to the section as amended.

INFORMATIVE DIGEST/PLAIN ENGLISH OVERVIEW — SUMMARY OF PROPOSED REGULATION

DRE is responsible for the licensing of real estate brokers and salespersons in the State of California. In this role, DRE evaluates the fitness of an individual applicant or licensee for real estate licensure where DRE becomes aware of criminal convictions or other license discipline imposed upon the applicant or licensee.

In language that remains in effect until July 1, 2020, Code section 480 authorizes specified licensing agencies to deny an application for a license where the applicant was previously convicted of a crime substantially related to the profession for which the applicant seeks a license. Correspondingly, section 490 currently authorizes the same licensing agencies to discipline an existing license when an existing licensee is convicted of a crime substantially related to the licensed profession. Current section 481 requires the specified licensing agencies to set out standards that identify which crimes or acts are substantially related to the regulated profession. DRE's Criteria for Substantial Relationship appear in Title 10 of the California Code of Regulations, Chapter 6, Section 2910.

AB 2138 (Chiu, Chapter 995, Statutes of 2018) amended sections 480 and 481 of the Code. Effective on July 1, 2020, the amendments limit the specified licens-

ing agencies' use of past criminal convictions in denying license applications. The amendments also necessitate the amendment of existing Criteria for Substantial Relationship, including DRE's regulation section 2910. Further, the revised statute also calls for several specific licensing fields involving financial regulation, including real estate licensure, to define the financial crimes that those agencies may use to deny a license beyond the seven−year maximum time limit imposed by AB 2138 on the use of other types of convictions. DRE defines this term by adding proposed Section 2910.5 to the Regulations.

Finally, existing references to "Bureau" or "department" in the existing section 2910 of the Regulations are amended to "Department" for consistency.

Anticipated Benefits of the Proposed Regulation

The proposed language brings the existing DRE Criteria for Substantial Relationship into consistency with the updated statutory standard. Also, the proposed amendment will make specific the scope of the financial convictions that still may be used to deny a real estate license application beyond the seven−year limit on corresponding use of other convictions, allowing DRE to remain in harmony with the federally−established scope of the Secure and Fair Enforcement for Mortgage Licensing Act of 2008 (Public Law 110−289). ("SAFE Act".)

Evaluation of Inconsistency/Incompatibility with Existing State Regulations

The Commissioner has determined that these proposed regulations are not inconsistent or incompatible with existing regulations. After conducting a review for any regulations that would relate to criteria for determining the substantial relationship of an applicant's or licensee's criminal convictions or license discipline to the practice of real estate, the Commissioner has concluded that these are the only State of California regulations relating to the subject.

DISCLOSURES REGARDING THE PROPOSED ACTION

The Commissioner has made the following determinations:

Mandate on local agencies and school districts: None.

Cost or savings to any state agency: None.

Cost to any local agency or school district that must be reimbursed in accordance with Government Code sections 17500 through 17630: None.

Other nondiscretionary cost or savings imposed on local agencies: None.

Cost or savings in federal funding to the state: None.

Cost impacts on a representative private person or business: None.

Significant, statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states: None.

Significant effect on housing costs: None.

RESULTS OF THE ECONOMIC IMPACT ANALYSIS/ASSESSMENT

The Commissioner concludes that it is (1) unlikely that the proposal will eliminate any jobs for real estate licensees or associated professions, (2) unlikely that the proposal will create jobs,[1] (3) unlikely the proposal will create new businesses of any sort, (4) unlikely that the proposal will eliminate any existing businesses, and (5) unlikely that the proposed regulations will result in the expansion of businesses currently doing business in the state.

BENEFITS OF THE PROPOSED ACTION

The stated goal of AB 2138 was to increase access to licensure for persons with criminal convictions in their background. Although DRE's Criteria for Rehabilitation includes provisions that already encompass much of the scope of the standard set by AB 2138, this proposal will harmonize DRE's Criteria for Substantial Relationship with the new AB 2138 and, prospectively, allow for some issuance of licenses where present law would limit such access. The proposed regulatory amendments and addition will not benefit worker safety or the state's environment.

SMALL BUSINESS DETERMINATION

The Commissioner has determined that there is no fiscal impact to small businesses resulting from this proposed regulatory amendment. The amendments serve only to implement the statutory standard, rather than impose a substantial change in that standard.

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code section 11346.5, subdivision (a)(13), the Commissioner must determine that no reasonable alternative they considered, or that has otherwise been identified and brought

[1] Although AB 2138 appears to modify the screening standards applied to real estate license applicants, DRE's existing Criteria for Rehabilitation (sections 2911 and 2912 of the Regulations) already encompass almost all of the scope of the statute that will go into effect on July 1, 2020. DRE predicts that practical impact of these changes on applicants will be minimal.

to the attention of DRE, would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost−effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

DRE invites interested persons to present statements or arguments with respect to alternatives to the proposed regulation during the written comment period.

CONTACT PERSON

Inquiries concerning this action may be directed to Daniel Kehew at (916) 576−7842, or via email at DRERegs@dre.ca.gov. The backup contact person is Stephen Lerner at (916) 576−8100.

AVAILABILITY OF STATEMENT OF REASONS, TEXT OF PROPOSED REGULATIONS, AND RULEMAKING FILE

DRE will have the entire rulemaking file available for inspection and copying throughout the rulemaking process at its headquarters office: 1651 Exposition Boulevard, Sacramento, California. As of the date this notice is published in the Notice Register, the rulemaking file consists of this notice, the proposed text of the regulations, the initial statement of reasons, and the Form 400 under which the package was submitted to the Office of Administrative Law for publication. Copies may be obtained by contacting Daniel E. Kehew at the mailing address and email address listed above.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

After considering all timely and relevant comments received, the Commissioner may adopt the proposed regulations substantially as described in this notice. If the Commissioner makes modification that are sufficiently related to the originally proposed text, DRE will make the modified text (with the changes clearly indicated) available to the public for at least 15 days before the Commissioner adopts the regulation as revised. A request for a copy of any modified regulation(s) should be addressed to the contact person designated above. The Commissioner will accept written comments on the modified regulation for 15 days after the date on which they are made available.

AVAILABILITY OF THE FINAL STATEMENT OF REASONS

Upon its completion, the Final Statement of Reasons will be available and copies may be requested from the contact person named in this notice or may be accessed on the website listed below.

AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of the notice, the initial statement of reasons, and the text of the regulations in underline and strikeout can be accessed through DRE's website at www.dre.ca.gov.

TITLE 15. DEPARTMENT OF CORRECTIONS AND REHABILITATION

NOTICE IS HEREBY GIVEN that the Secretary of the California Department of Corrections and Rehabilitation (CDCR or Department), proposes to amend Section 3436, and adopt new Section 3436.1 into Title 15, Division 3, Chapter 1, regarding Limited Term Light Duty Assignments and Temporary Modified Work Assignments.

PUBLIC COMMENT PERIOD

The public comment period begins **July 3, 2020** and closes on **August 21, 2020.** Any person may submit written comments by mail addressed to the primary contact person listed below, or by email to rpmb@cdcr.ca.gov, before the close of the comment period. For questions regarding the subject matter of the regulations, call the program contact person listed below.

No public hearing is scheduled for these proposed regulations; however, pursuant to Government Code Section 11346.8, any interested person or their duly authorized representative may request a public hearing, no later than 15 days prior to the close of the written comment period.

CONTACT PERSONS

Primary Contact
S. Pollock
Telephone: (916) 445−2308
Regulation and Policy
Management Branch
P.O. Box 942883
Sacramento, CA 94283−0001

Back−Up
Y. Sun
Telephone: (916) 445−2269
Regulation and Policy
Management Branch
P.O. Box 942883
Sacramento, CA 94283−0001

Program Contact
L. Mahannah
Telephone: (916) 341−7041
Employee Health and Wellness

AUTHORITY AND REFERENCE

Government Code Section 12838.5 provides that commencing July 1, 2005, CDCR succeeds to, and is vested with, all the powers, functions, duties, responsibilities, obligations, liabilities, and jurisdiction of abolished predecessor entities, such as: Department of Corrections, Department of the Youth Authority, and Board of Corrections.

Penal Code (PC) Section 5000 provides that commencing July 1, 2005, any reference to Department of Corrections in this or any code, refers to the CDCR, Division of Adult Operations. **PC Section 5050** provides that commencing July 1, 2005, any reference to the Director of Corrections in this or any other code, refers to the Secretary of the CDCR. As of that date, the office of the Director of Corrections is abolished.

PC Section 5054 provides that commencing July 1, 2005, the supervision, management, and control of the State prisons, and the responsibility for the care, custody, treatment, training, discipline, and employment of persons confined therein are vested in the Secretary of the CDCR. **PC Section 5055** provides that commencing July 1, 2005, all powers and duties previously granted to and imposed upon the Department of Corrections shall be exercised by the Secretary of the CDCR. **PC Section 5058** authorizes the Director to prescribe and amend rules and regulations for the administration of prisons and for the administration of the parole of persons. **PC Section 5058.3** authorizes the Director to certify in a written statement filed with Office of Administrative Law that operational needs of the Department require adoption, amendment, or repeal of a regulation on an emergency basis.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

This rulemaking action amends California Code of Regulations, Title 15, Section 3436, concerning Limited Term Light Duty Assignments (LTLDA), and adopts new Section 3436.1 concerning Temporary Modified Work Assignments (TMWA). Revisions to LTLDA involve a change to the length of an LTLDA for which an employee may be off duty due to a temporary disability which cannot be reasonably accommodated. New provisions concerning a TMWA provide employees the opportunity of a temporary assignment with work duties which meet the employee's documented medical limitation(s) or restriction(s) when employees cannot be accommodated with a reasonable accommodation or LTLDA.

Currently, Title 15, Section 3436 allows placement in an LTLDA for a maximum of 60 days. These amended regulations will expand the length of time eligible employees may be placed into an LTLDA from the current 60 days to a maximum of 360 days. This will allow the Department to use an LTLDA to accommodate an employee for a longer period of time when their documented medical limitation(s) or restriction(s) are still prevalent.

This action will:

- Provide new descriptive language and provisions for an LTLDA.
- Provide for a potential extension of an LTLDA, up to 360 days, on a case−by−case basis, and with supporting documentation from the employee's health care provider.
- Adopt a new section for TMWA.
- Provide that a TMWA will be considered when an employee cannot be accommodated with a reasonable accommodation or LTLDA.
- Establish provisions for TMWAs.

DOCUMENTS INCORPORATED BY REFERENCE

N/A

SPECIFIC BENEFITS ANTICIPATED BY THE PROPOSED REGULATIONS

The proposed regulations will benefit CDCR and California Correctional Health Care Services (CCHCS) employees by allowing them to potentially extend their LTLDA or TMWA up to 360 days. This will reduce financial impact to employees during temporary disability, injury, or illness when they cannot afford to demote, take medical leave due to not having sufficient personal leave credits to cover their absence, take an unpaid leave of absence, or leave the Department. Additionally, it will benefit the Department by reducing negative impact when employees are absent for extended periods of time due to temporary disability, injury or illness. And, the Department will benefit by retaining valuable

trained employees that provide necessary services to accomplish the critical mission of the Department.

EVALUATION OF CONSISTENCY/COMPATIBILITY WITH EXISTING LAWS AND REGULATIONS

Pursuant to Government Code 11346.5(a)(3)(D), the Department performed a search of existing regulations and determined that the proposed regulations are neither inconsistent nor incompatible with existing regulations.

LOCAL MANDATES

This action imposes no mandates on local agencies or school districts, or a mandate which requires reimbursement of costs or savings pursuant to Government Code Sections 17500−17630.

FISCAL IMPACT STATEMENT

- Cost or savings to any state agency: *$27.8 million cost annually estimated.*
- Cost to any local agency or school district that is required to be reimbursed: *None*.
- Other nondiscretionary cost or savings imposed on local agencies: *None*.
- Cost or savings in federal funding to the state: *None*.

EFFECT ON HOUSING COSTS

The Department has made an initial determination that the proposed action will have no significant effect on housing costs.

COST IMPACTS ON REPRESENTATIVE PRIVATE PERSONS OR BUSINESSES

The Department is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT ON BUSINESS

The Department has made an initial determination that the proposed regulations will not have a significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states, because the proposed regulations place no obligations or requirements on any business.

EFFECT ON SMALL BUSINESSES

The Department has determined that the proposed regulations will not affect small businesses. This action has no significant adverse economic impact on small business because they place no obligations or requirements on any business.

RESULTS OF THE ECONOMIC IMPACT ASSESSMENT

The Department believes there will be economic impact with the proposed regulations, as other full duty employees will have to be hired behind an employee who is removed from their regular position and placed in a TMWA within the CDCR or CCHCS. CDCR and CCHCS estimate costs of $27.8 million annually, and will request funding through the State's budgetary process.

The Department has determined that the proposed regulation will have no effect on the creation of new, or the elimination of existing, jobs or businesses within California, or effect the expansion of businesses currently doing business in California. The Department has determined that the proposed regulation will have no effect on the State's environment. These regulations may benefit the health and welfare, and worker safety of California residents by allowing for CDCR and CCHCS employees that need an LTLDA or TMWA accommodation to possibly extend their accommodation up to a maximum of 360 days. By extending their LTLDA or TMWA, this will benefit the health and welfare of the employee by allowing them to continue working in an assignment that will be conducive to their health needs; and it will benefit worker safety by not creating a situation where a re−injury/further illness could occur had the employee been forced to return to their regular assignment duties before they were physically able to do so.

CONSIDERATION OF ALTERNATIVES

The Department must determine 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 to affected private persons than the proposed regulatory action, or would be more cost−effective to affected private persons and equally effective in implementing the statutory policy

or other provisions of law. Interested persons are invited to present statements or arguments with respect to any alternatives to the changes proposed at the scheduled hearing or during the written comment period.

CDCR and CCHCS considered not amending current regulations, and retaining the existing language in Title 15, Section 3436. However, that option was rejected because CDCR and CCHCS would continue to lose the vital services of employees who would be out for extended periods after a 60−day LTLDA expired, thereby negatively impacting CDCR's ability to accomplish its critical mission. Also, employees would be required to continue to use personal leave, temporarily demote to positions in which they are able to perform the essential functions, request an unpaid leave of absence, or choose to leave CDCR.

CDCR and CCHCS also considered extending the duration of the LTLDA without adding the option of a TMWA. However, that alternative was rejected because of concern that insufficient vacant budgeted positions would be available for all employees who were eligible for an LTLDA.

AVAILABILITY OF PROPOSED TEXT AND INITIAL STATEMENT OF REASONS

The Department has prepared and will make available the text and the Initial Statement of Reasons (ISOR) of the proposed regulations. The rulemaking file for this regulatory action, which contains those items and all information on which the proposal is based (i.e., rulemaking file), is available to the public upon request directed to the Department's contact person. The proposed text, ISOR, and Notice of Proposed Action will also be made available on the Department's website: www.cdcr.ca.gov.

AVAILABILITY OF THE FINAL STATEMENT OF REASONS

Following its preparation, a copy of the Final Statement of Reasons may be obtained from the Department's contact person.

AVAILABILITY OF CHANGES TO PROPOSED TEXT

After considering all timely and relevant comments received, the Department may adopt the proposed regulations substantially as described in this Notice. If the Department makes modifications which are sufficiently related to the originally proposed text, it will make the modified text, with the changes clearly indicated, available to the public for at least 15 days before the Department adopts, amends or repeals the regulations as revised. Requests for copies of any modified regulation text should be directed to the contact person indicated in this Notice. The Department will accept written comments on the modified regulations for at least 15 days after the date on which they are made available.

TITLE 16. BOARD OF PHARMACY

NOTICE IS HEREBY GIVEN that the California State Board of Pharmacy (board) is proposing to take the rulemaking action described below under the heading Informative Digest/Policy Statement Overview. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e−mail to the addresses listed under Contact Person in this Notice, must be received by the board at its office by August 17, 2020.

The board has not scheduled a public hearing on this proposed action. The board will, however, hold a hearing if it receives a written request for a public hearing from any interested person, or his or her authorized representative, no later than 15 days prior to the close of the written comment period.

The board may, after considering all timely and relevant comments, adopt the proposed regulations substantially as described in this notice, or may modify the proposed regulations if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as the contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Section 4005, 4075, 4114, 4119.11, and 4427.7 of the Business and Professions Code (B&P) and Section 2 of Chapter 677, Statutes of 2000 authorize the board to adopt these regulations. The proposed regulations implement, interpret, and make specific sections 4008, 4017.3, 4021, 4022, 4036, 4037, 4038, 4040, 4050, 4051, 4052, 4059, 4070, 4076, 4081, 4101, 4105, 4107, 4413, 4119.1, 4119.11, 4125, 4126, 4180, 4186, 4305, 4330, 4332, 4333, 4416, 4117, 4119.1, 4119.11, 4125, 4126, 4427, 4427.1, 4427.2, 4427.3, 4427.4, 4427.5, 4427.6, 4427.7 and 4427.8 of the Business and Professions Code.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

The California State Board of Pharmacy (board) is a state agency vested with the authority to regulate the

pharmacy industry, including pharmacies, pharmacists, and pharmacy technicians (Business and Professions Code (B&P) section 4000, et seq.). The board's mandate and its mission is to protect the public (B&P section 4001.1).

Existing law at B&P section 4105.5 establishes the requirement that a pharmacy that owns or provides dangerous drugs to an automated drug delivery system (ADDS) must register the ADDS with the board within 30 days of installation of the device.

Assembly Bill 2037 (Bonta, Statutes of 2018, Chapter 647) added, among other things, B&P Section 4119.11. This new statute established two separate classifications of ADDS, specifically, Automated Patient Dispensing System (ADPS) and Automated Unit Dose System (AUDS). Additionally, Senate Bill (SB) 1447 (Hernandez, Chapter 666, Statutes of 2018) added, among other things, B&P Sections 4427.2, 4427.3, 4427.4, 4427.6, and 4427.7. These new statutes established the board's authority to issue an ADDS license; established ownership, placement, and operation requirements; established recordkeeping and quality assurance requirements; and established the requirement for the completion of an annual self−assessment by the pharmacy holding the ADDS license.

This proposal will amend 16 CCR section 1711 to require that records related to the use of an ADDS developed as part of the quality assurance review, established by B&P section 4427.6(i), be submitted to the board. Additionally, this proposal will amend 16 CCR section 1713 to align the board's regulation with the newly established APDS license and clarify its use. Finally, this proposal will add 16 CCR Section 1715.1 to identify the specific requirements for the completion of the self−assessment with respect to the use of an ADDS as required by B&P section 4427.7.

ANTICIPATED BENEFITS OF THE PROPOSED REGULATIONS

Protection of the public is the board's highest priority in exercising its licensing, regulatory and disciplinary functions. This regulatory proposal benefits the health and welfare of California residents, as well as benefiting employee safety. The proposed regulation will ensure that the board is aware of possible quality issues and/or complaints related to the use of an ADDS. This will allow the board to inspect or investigate possible concerns with respect to the use of the systems. Additionally, the proposed regulation provides clarity to the regulated public with respect to the use of an APDS. This benefits the health and welfare of California residents by ensuring that they are properly counseled and that their medications are appropriately labeled and accurately dispensed. Finally, the proposal identifies the specific requirements for the self−assessment form. The self−assessment form aids licensees in assessing their compliance with federal and state law and regulations. This annual review can increase compliance and accountability, which will result in increased consumer safety and improved operations with respect to employee safety. The Board determined that this proposal will not impact the state's environment.

CONSISTENCY AND COMPATIBILITY WITH EXISTING STATE REGULATIONS

During the process of developing these regulations and amendments, the board conducted a search of similar regulations on this topic and concluded that these regulations are neither inconsistent nor incompatible with existing state regulations.

INCORPORATION BY REFERENCE

Automated Drug Delivery System Self−Assessment [17M−112 (Rev. 12/18)].

FISCAL IMPACT AND RELATED ESTIMATES

Fiscal Impact on Public Agencies Including Costs/Savings to State Agencies or Costs/Savings in Federal Funding to the State: None.

Nondiscretionary Costs/Savings to Local Agencies: None.

Local Mandate: None.

Cost to Any Local Agency or School District for Which Government Code Sections 17500−17630 Require Reimbursement: None.

Business Impact:

The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states. This proposal does not impose a fee; however, there may be a minor cost to businesses related to paper, storage, and staff time to complete the self−assessment and to submit the quality assurance records to the board.

Cost Impact on Representative Private Person or Business:

The board estimates that there may be a minimal expense to the pharmacy for supply costs to complete the self−assessment form (i.e. paper) and the time it will take the pharmacist−in−charge (PIC) to complete the self−assessment evaluation. The board estimates that the process should not take more than an hour or two, unless the licensed premises is out of compliance,

which will require additional time to identify and implement corrective actions. The proposal does require that any record related to the use of an ADDS must also be submitted to the board within 30 days of completion of the quality assurance review. This submission can be done via mail or fax. The cost associated would be the cost of the paper and the staff time to print and mail or fax the documents to the board. The board believes these costs to be minor and absorbable. The board anticipates no costs to an individual.

Effect on Housing Costs: None.

EFFECT ON SMALL BUSINESS

The board does not have nor does it maintain data to determine if any of its licensees are a "small business" as defined in Government Code § 11342.610. However, the board anticipates that most, if not all, of the pharmacies that will utilize an ADDS system will not be small businesses. While it is possible for a small business pharmacy to operate an ADDS, it is unlikely due to the size of the small business and the staffing requirements to maintain complete oversight and ensure proper operation of the device.

RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS

Impact on Jobs/New Businesses:

The board concludes that:

(1) this proposal will not create jobs within California;
(2) this proposal will not eliminate jobs within California;
(3) this proposal will not create new businesses within California;
(4) this proposal will not eliminate of existing businesses within California;
(5) this proposal will not expand businesses currently doing business in the State of California.

Benefits of Regulation:

The board has determined that this regulatory proposal benefits the health and welfare of California residents, and worker safety. The proposed regulation will ensure that the board is aware of possible quality issues and/or complaints made with respect to the use of ADDS by requiring the quality assurance reports be submitted to the board. This will allow the board to inspect or investigate possible concerns with respect to the use of the systems. Additionally, the proposal identifies the specific requirements for the self−assessment form. The self−assessment form aids licensees in assessing their compliance with federal and state law and regulations. As the PIC completes the self−assessment form, they will identify any areas where the pharmacy's use of an ADDS may be out of compliance. This awareness can increase self−correction by providing useful information to the PIC about controlling statutes and regulations. This periodic review and accountability will result in increased consumer safety and will improve operations with respect to employee safety. This proposal will not impact the state's environment.

CONSIDERATION OF ALTERNATIVES

The board must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposal described in this Notice, or would be more cost−effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Any interested person may present statements or arguments in writing relevant to the above determinations at the address listed for the Contact Person during the written comment period.

INITIAL STATEMENT OF REASONS AND INFORMATION

The board has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations, and any document incorporated by reference, and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained upon request from the Board of Pharmacy at 2720 Gateway Oaks Drive, Ste. 100, Sacramento, California 95833, or from the Board of Pharmacy's website at http://www.pharmacy.ca.gov.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared by making a written re-

quest to the contact person named below, or by accessing the website listed below.

CONTACT PERSON

Inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:
Lori Martinez

Address:
2720 Gateway Oaks Drive Ste. 100
Sacramento, CA 95833

Phone No.:
(916) 518−3078

Fax No.:
(916) 574−8618

E−Mail Address:
Lori.Martinez@dca.ca.gov

The backup contact person is:

Name:
Debbie Damoth

Address:
2720 Gateway Oaks Drive Ste. 100
Sacramento, CA 95833

Phone No.:
(916) 518−3090

Fax No.:
(916) 574−8618

E−Mail Address:
Debbie.Damoth@dca.ca.gov

WEBSITE ACCESS

Materials regarding this proposal can be found at the board's website: www.pharmacy.ca.gov.

TITLE 22. DEPARTMENT OF PUBLIC HEALTH

DPH−11−023 Adverse Events

Notice is hereby given that the California Department of Public Health (Department) is proposing the regulation described below. This notice of proposed rulemaking commences a rulemaking to make the regulations permanent after considering all comments, objections, and recommendations regarding the regulation.

PUBLIC PROCEEDINGS

The Department is conducting a 45−day written public proceeding during which time any interested person or such person's duly authorized representative may present statements, arguments or contentions (all of which are hereinafter referred to as comments) relevant to the action described in the Informative Digest/Policy Statement Overview section of this notice.

To request copies of the regulatory proposal in an alternate format, please write or call: Hannah Strom−Martin, Office of Regulations, 1415 L Street Suite 500, Sacramento, CA 95814, at (916) 440−7371, email to hannah.strom−martin@cdph.ca.gov or use the California Relay Service by dialing 711.

WRITTEN COMMENT PERIOD

Written comments pertaining to this proposal, regardless of the method of transmittal, must be received by Office of Regulations by 5:00 p.m. on August 18, 2020, which is hereby designated as the close of the written comment period. Comments received after this date will not be considered timely.

Written comments may be submitted as follows:

1. By email to: regulations@cdph.ca.gov. It is requested that email transmission of comments, particularly those with attachments, contain the regulation package identifier "DPH−11−023 Adverse Events Reporting" in the subject line to facilitate timely identification and review of the comment;
2. By fax transmission to: (916) 319−9821;
3. By postal service or hand delivered to: California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814.

All submitted comments should include the regulation package identifier, **"DPH−11−023 Adverse Events Reporting,"** along with the commentor's name and email or mailing address.

PUBLIC HEARING

The Department has not scheduled a public hearing on this proposed action. However, the Department will hold a hearing if it receives a written request for a public hearing from any interested person, or his or her authorized representative, no later than 15 days prior to the close of the written comment period

ASSISTIVE SERVICES

For individuals with disabilities, the Department will provide assistive services such as the conversion of

written materials into Braille, large print, audiocassette, and compute disk. For public hearings, assistive services can include sign−language interpretation, real−time captioning, note takes, and reading or writing assistance. To request these assistive services, please call (916) 558−1710 or (California Relay at 711 or 1−800−735−2929), email regulations@cdph.ca.gov, or write to the Office of Regulations at the address noted above. Note: The range of assistive services available may be limited if requests are made less than 10 business days prior to a public hearing.

AUTHORITY AND REFERENCE

Health and Safety Code section 1275 requires the Department to adopt, amend, or repeal regulations to carry out the purposes and intent of Chapter 2 (Licensing Provision) of the Health and Safety Code. Health and Safety Code sections 131000, 131050, 131051, 131052 and 131200 specify the Department's authority vested by the California Public Health Act of 2006, SB 162 (Chapter 241, Statutes of 2006), effective July 1, 2007.

Health and Safety Code section 1250 defines the licensure categories for general acute care hospital, acute psychiatric hospital, and special hospital. The proposed regulations implement, interpret and make specific Health and Safety Code sections 1279.1, 1279.2, 1279.3, and 1279.6, which require adverse event (AE) reporting, Departmental investigation, and public posting of information regarding substantiated AE, and the preparation and implementation of patient safety plans by hospitals.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Summary of Proposal

Adverse Events are serious reportable events that often result in patient deaths or serious disabilities. Health and Safety Code section 1279.1 requires that AEs occurring in general acute care hospitals (GACHs), acute psychiatric hospitals (APHs), and special hospitals (SHs) (collectively, the hospitals), be reported to the Department. Under Health and Safety Code section 1279.2, the Department is required to investigate AE reports and complaints regarding patient safety. The proposed regulations would clarify the categories, define terms within each AE category reportable by hospitals to the Department, and prescribes the use of the Department's electronic web−based portal for reporting AEs.

Background

The California State Legislature enacted Senate Bill (SB) 1301 (Chapter 647, Statutes of 2006),[1] in part, to require the Department, successor to the Department of Health Services,[2] to implement a statewide system for reporting AEs to the Department. SB 1301 enacted, in part, Health and Safety Code section 1279.1, which specifies the seven categories of AEs required to be reported by hospitals to the Department within prescribed timelines.

SB 1301 also enacted Health and Safety Code section 1279.2, prescribing the Department's responsibility to investigate AE reports and complaints. Consequently, the proposed regulations specify Department actions and timelines prescribed within the statute for onsite inspection of reports for ongoing threats of imminent danger of death or serious bodily harm, or an investigation of a report absent the above−mentioned ongoing threat.

The Legislature also enacted SB 158 (Chapter 294, Statutes of 2008) requiring, in part, that hospitals develop, implement, and comply with a patient safety plan to improve the health and safety of patients and reduce preventable patient safety events.[3] The patient safety plan must include a reporting system for patient safety events, pursuant to Health and Safety Code section 1279.6.

Enforcement of the proposed AE regulations is the responsibility of the Department's Center for Health Care Quality (CHCQ), Licensing and Certification Program (L&C), pursuant to Health and Safety Code section 131051(b)(1) through (b)(3). L&C's mission includes promoting the highest quality of health care in licensed hospitals. L&C's goals include consistent oversight of hospitals to ensure compliance with state and federal standards while promoting patient safety.

In response to the Department's pre−notice hearing on November 24, 2010, the regulated community recommended the AE definitions by the National Quality Forum (NQF), *Serious Reportable Events in Healthcare* — 2006 *Update: A Consensus Report* be

[1] SB 1301 enacted Health and Safety Code §1279.1, §1279.2, §1279.3 and §1280.4.

[2] Pursuant to SB 162 (Chapter 241, Statutes of 2006), which reorganized the former Department of Health Services into the Department of Public Health and the Department of Health Care Services.

[3] Health and Safety Code §1279.6(a) also applies to skilled nursing facilities (SNF), licensed pursuant to Health and Safety Code §1250(c) and defined as a long−term facility pursuant to Health and Safety Code §1418(a)(1). A separate regulatory action for SNF patient safety is planned because patient safety issues in long−term care differ from acute care.

used to define terms in these proposed regulations (Document relied upon, NQF *2006 Update*).[4]

Given NQF's expertise and the unique role the organization has in improving the quality of health care, the Department determined that using these industry–wide accepted definitions would be beneficial, as they would likely be familiar to hospitals. The NQF released a 2011 Update. Consequently, the proposed definitions are modeled after the NQF 2011 Update, when compatible with Health and Safety Code section 1279.1 AE categories and terms.

Problem Statement

Health and Safety Code sections 1279.1, 1279.2, and 1279.6 applicable to AEs are ambiguous and subject to interpretation. Health and Safety Code section 1279.1 includes medical terminology requiring definition for clarity and consistency in reporting and investigating AEs. Health and Safety Code section 1279.2 prescribes, in part, the Department's responsibility for investigating AE reports and complaints, but does not specify the hospital's responsibility to provide information to the Department. Health and Safety Code section 1279.6 requires the hospital to implement a culture of safety by developing, implementing, and complying with a patient safety plan, but does not prescribe how the plan is to be developed, or how the culture of safety is to be assessed.

To implement Health and Safety Code sections 1279.1, 1279.2, and 1279.6, the proposed regulations establish a consistent statewide system requiring hospitals to identify, report, and correct systemic problems contributing to preventable patient safety events, including AEs.[5] Additionally, hospitals are required to establish systemic processes to support a culture of safety, including internal reporting and documentation of preventable patient safety events, conducting a root cause analysis to prevent recurrence, and performing annual assessments of the hospital's culture of safety.

Objectives (Goals) of the Regulation

The proposed regulations clarify and specify statutory requirements for the purpose of improving patient safety in hospitals and encouraging a culture of safety in hospitals by:

- Establishing AE definitions in Title 22 to provide clarity and consistency in applying medical terms to reporting requirements.
- Defining and clarifying the reporting requirements and the situational circumstances regarding AEs.
- Requiring a hospital to use the Department's secure electronic web–based portal for transmitting AE reports to the Department, preserving patient confidentiality.
- Specifying reporting, investigation, or inspection timelines for AEs.
- Requiring hospitals to conduct a root cause analysis to identify systemic problems and implement corrective actions to prevent future occurrence of AEs.
- Requiring hospitals to annually assess the hospital's culture of safety.

Anticipated Benefits

Anticipated benefits from the proposed regulations are to provide transparency and consistency for reporting of AEs. The proposed regulations are intended to improve reporting, accountability, and patient safety by establishing clear and consistent statewide reporting standards, endorsed by the NQF, for detection and response to systemic problems and/or AEs, thereby promoting a culture of safety, and improved public accountability and trust.

EVALUATION AS TO WHETHER THE PROPOSED REGULATIONS ARE INCONSISTENT OR INCOMPATIBLE WITH EXISTING STATE AND FEDERAL REGULATIONS

The Department evaluated whether the proposed regulations are inconsistent or incompatible with existing state and federal regulations. This evaluation included a review of the Department's laws, as well as those statutes and regulations related to AEs. The Department has determined that no other state regulation addresses the same subject matter, and there are no existing state or federal regulations with which the proposed regulations conflict or with which they are incompatible.

FORMS INCORPORATED BY REFERENCE

None.

[4] The NQF is a nonprofit, nonpartisan, public service organization, created in 1999 in response to recommendations from the *President's Advisory Commission on Consumer Protection and Health Care Industry.* The NQF developed into a collaborative organization at the forefront of quality improvement efforts in health care. The NQF builds consensus on national priorities and performance improvement goals by endorsing national standards for measurement and public reporting of performance and promotes national goals through education and outreach programs. The NQF is a nationally recognized authority on events associated with patient death or serious disabilities that continue to recur in health care.

[5] Preventative patient safety events are defined at Health and Safety Code §1279.6(c).

MANDATED BY FEDERAL LAW OR REGULATIONS

Not applicable.

OTHER STATUTORY REQUIREMENTS

Not applicable.

LOCAL MANDATE

The Department has determined that this regulatory 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.

DISCLOSURES REGARDING THE PROPOSED ACTION

FISCAL IMPACT ESTIMATES

A) Cost to any local agencies or school districts that must be reimbursed pursuant to Section 17561 of Government Code:

The proposed regulations do not impose costs on any local agency or school district for which reimbursement would be required pursuant to part 7 (commencing with section 17500) of division 4 of the Government Code.

B) The cost or savings to any state agency:

The Department has determined there may be a nominal cost benefit to the Department as a result of Department staff no longer needing to contact hospitals to request additional information on AEs.

C) Impact on any cost or savings in federal funding of the program:

There is no federal funding affected by the proposed regulatory action.

D) Other nondiscretionary costs or savings imposed on local agencies:

The proposed regulations do not impose other nondiscretionary costs or savings on any local agencies.

HOUSING COSTS

The Department has determined that the regulations will not have an impact on housing costs.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE

The Department has made an initial determination that these regulations would not have a significant statewide adverse economic impact directly affecting businesses, and individuals, including the ability of California businesses to compete with businesses in other states.

STATEMENT OF THE RESULTS OF THE ECONOMIC IMPACT ASSESSMENT

The proposal provides transparency and consistency for reporting of AEs. The proposed regulations improve reporting, accountability, and patient safety by establishing clear and consistent statewide reporting standards, endorsed by the NQF, for detection and response to systemic problems and/or AEs, thereby promoting a culture of safety, and improved public accountability and trust. The proposed regulation does not contribute negatively to the state's environment because it does not affect the environment.

The benefits of the regulations to the health and safety of California residents far outweigh the costs associated with hospitals reporting of AEs and the development and implementation of patient safety plans, as the following demonstrates:

An abstract of a medical journal article, A comprehensive patient safety program can significantly reduce preventable harm, associated costs, and hospital mortality, reported on the evaluation of "the effectiveness of a hospital−wide initiative to improve patient safety by implementing high−reliability practices as part of a quality improvement (QI) program aimed at reducing all preventable harm." The evaluation concluded, "Substantial reductions in serious safety event rate, preventable harm, hospital mortality, and cost were seen after implementation . . . Measurable improvements in the safety culture were noted as well."

The New Jersey Hospital Association (NJHA) reported "that the three−year Partnership for Patients−New Jersey, part of the nationwide Partnership for Patients project spearheaded by the [CMS], led to 13,730 instances where patient harm was averted and a total savings of $120 million in healthcare costs, based on data from the Agency for Healthcare Research and Quality (AHRQ)."

A review of AE data for California hospitals between state fiscal year (FY) 2007−08 through FY 2014−15 annually report between 611 and 1282 events. Implementation of a patient safety plan incorporating a culture of safety demonstrates the potential to improve patient safety and reduce health care costs.

The Department has made an initial determination that these proposed regulations would have no significant direct economic impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states because the proposed regulations would not significantly affect:

A) The creation or elimination of jobs within the State of California;

B) The creation of new businesses or the elimination of existing businesses within the State of California; or

C) The expansion of businesses currently doing business within the State of California.

COST IMPACTS ON REPRESENTATIVE PERSON OR BUSINESS

The Department is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action. Hospitals must already report AEs to the Department, and the purpose of these proposed regulations is to clarify terms, reporting requirements, and investigation parameters.

REPORTING REQUIREMENT

While hospitals are required to report AEs under existing statute, this regulation would make specific the details of these requirements and prescribe the use of the Department's electronic web−based portal (portal) for reporting AEs. The Department has found that reporting AEs via the portal protects data integrity and is in line with current industry practices designed to safeguard public health.

The Department finds that it is necessary for the health, safety, or welfare of the people of this state that proposed sections 70970, 70972, 71565, and 71567, which require a report, apply to businesses.

EFFECT ON SMALL BUSINESS

The Department has made an initial determination that there is an effect on small business (hospitals), because all GACHs, APHs, and SHs fall under the regulation parameters despite size and location. However, the Legislature included specific guidelines and considerations within the statute for small and rural hospitals if a penalty occurs relative to an AE report, pursuant to Health and Safety Code, section 1279.2(f). This consideration includes alternatives provided by the Department for options in reducing the penalty amount to avoid an excessive financial burden and protect the quality of patient care.[6]

MANDATED USE OF SPECIFIC TECHNOLOGIES, EQUIPMENT, ACTIONS, OR PROCEDURES

The Department developed an electronic web−based portal (portal) for reporting of AEs, which is available on the Department's website and does not require a fee to use or enroll. Hospitals must register to use the portal, and redacted database information is then available for use by hospitals for the purpose of analysis. The Department determined that use of the portal is convenient for hospitals, best ensures the security of the data, and is consistent with other reporting requirements for hospitals. The portal provides hospitals access to the Department's secure database, thereby facilitating the investigative process, reporting of results, and, ultimately, improvement in hospital patient safety.

In considering the use of a performance−based standard over the prescription of specific technologies and procedures, the Department determined that performance−based standards would be inadequate to address its duties as prescribed in statute.

ALTERNATIVES CONSIDERED

The Department has made an initial determination that no reasonable alternative considered by the Department, or otherwise identified and brought to the attention of the Department, would be (a) more effective in carrying out the purpose of the proposed regulations, (b) would be as effective and less burdensome to affected private persons than the proposed regulations, or (c) would be more cost−effective to affected private persons and equally effective for implementing Health and Safety Code section 1279.1, 1279.2, and 1279.6.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDIES, REPORTS OR DOCUMENTS RELIED UPON

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3. N.J. Hospital Quality Initiative Averts 13,730 Cases of Harm, $120 Million in Costs, Page 2. Retrieved from: http://www.njha.com/pressroom/

[6] Health and Safety Code §124840.

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12. Health Insurance Portability and Accountability Act, HIPAA. Retrieved from: https://www.dhcs.ca.gov/formsandpubs/laws/hipaa/Pages/1.10HIPAATitleInformation.aspx
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CONTACT PERSON

Inquiries regarding the substance of the proposed regulations described in this notice may be directed to Krisheidy Guerrero, email krisheidy.guerrero@cdph.ca.gov, phone (916) 327−0643. All other inquiries concerning the action described in this notice may be directed to Hannah Strom−Martin, Office of Regulations, at (916)440−7371, email hannah.strom−martin@cdph.ca.gov, or to the designated backup contact, Christy Correa, at (916) 440−7764, email christy.correa@cdph.ca.gov.

AVAILABILITY STATEMENTS

The Department has prepared and has available for public review an initial statement of reasons for the proposed regulations, all the information upon which the proposed regulations are based, and the text of the proposed regulations. The Office of Regulations, at the address previously noted, will be the location of public records, including reports, documentation, and other material related to the proposed regulations.

In order to request that a copy of this public notice, the regulation text, and the initial statement of reasons or alternate formats for these documents be mailed to you, please call (916) 440−7371 (or the California Relay Service at 711), or send an email to regulations@cdph.ca.gov, or write to the Office of Regulations at the address previously noted. Upon specific request, these documents will be made available in Braille, large print, audiocassette, or computer disk.

The full text of any regulation which is changed or modified from the express terms of the proposed action will be made available by the Department's Office of Regulations at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

A copy of the final statement of reasons when prepared will be available upon request from the Office of Regulations.

INTERNET ACCESS

Materials regarding the action described in this notice (including this public notice, the text of the proposed regulations, and the initial statement of reasons) that are available via the Internet may be accessed at www.cdph.ca.gov and by clicking on the following: Programs, Office of Regulations, and the Proposed Regulations link.

TITLE 22. DEPARTMENT OF PUBLIC HEALTH

DPH−11−009 Medical Information Breach

Notice is hereby given that the California Department of Public Health (Department) is proposing the regulation described below. This notice of proposed rulemaking commences a rulemaking to make the regulations

permanent after considering all comments, objections, and recommendations regarding the regulation.

PUBLIC PROCEEDINGS

The Department is conducting a 45−day written public proceeding during which time any interested person or such person's duly authorized representative may present statements, arguments or contentions (all of which are hereinafter referred to as comments) relevant to the action described in the Informative Digest/Policy Statement Overview section of this notice.

To request copies of the regulatory proposal in an alternate format, please write or call: Hannah Strom−Martin, Office of Regulations, 1415 L Street Suite 500, Sacramento, CA 95814, at (916) 440−7371, email to hannah.strom−martin@cdph.ca.gov or use the California Relay Service by dialing 711.

WRITTEN COMMENT PERIOD

Written comments pertaining to this proposal, regardless of the method of transmittal, must be received by Office of Regulations by 5:00 p.m. on August 18, 2020, which is hereby designated as the close of the written comment period. Comments received after this date will not be considered timely.

Written comments may be submitted as follows:

1. By email to: regulations@cdph.ca.gov. It is requested that email transmission of comments, particularly those with attachments, contain the regulation package identifier "DPH−11−009 Medical Information Breach" in the subject line to facilitate timely identification and review of the comment;
2. By fax transmission to: (916) 319−9821;
3. By postal service or hand delivered to: California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814.

All submitted comments should include the regulation package identifier, **"DPH−11−009 Medical Information Breach,"** along with the commentor's name and email or mailing address.

PUBLIC HEARING

A public hearing has not been scheduled for this rulemaking. However, the Department will conduct a hearing if a written request for a public hearing is received from any interested person, or his or her duly authorized representative, no later than 15 days prior to the close of the written comment period, pursuant to Government Code Section 11346.8.

ASSISTIVE SERVICES

For individuals with disabilities, the Department will provide assistive services such as the conversion of written materials into Braille, large print, audiocassette, and computer disk. For public hearings, assistive services can include sign−language interpretation, real−time captioning, notetakers, reading or writing assistance. To request these assistive services, please call (916) 558−1710 or (California Relay at 711 or 1−800−735−2929), email regulations@cdph.ca.gov, or write to the Office of Regulations at the address noted above. Note: The range of assistive services available may be limited if requests are made less than 10 business days prior to a public hearing.

AUTHORITY AND REFERENCE

The Department may promulgate the proposed regulation sections under the Department's regulatory authority provided by Health and Safety Code sections 131000, 131050, 131051, 131052 and 131200. The proposed regulation sections implement, interpret, and make specific Health and Safety Code section 1280.15.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Summary of Proposal

The California Department of Public Health (Department) proposes to adopt Chapter 13 (sections 79900−79905) of Division 5, Title 22 of the California Code of Regulations to establish standards for assessing breaches of a patient's medical information, and administrative penalties related to such breaches.

In 2008, Health and Safety Code section 1280.15 (Code) was enacted. The Code requires clinics, health facilities, home health agencies, and hospices (collectively, the health care facilities) to prevent the unlawful or unauthorized access to, and use or disclosure of, patient medical information (breaches). The Code authorizes the Department to assess administrative penalties against these health care facilities.

Background

The Department has regulatory oversight for more than 30 types of health care facilities and providers and approximately 10,000 facilities. The proposed regulations relate to the Department's assessment of administrative penalties for breaches of patient medical information by these health care facilities. Breaches of patient medical information are a serious national prob-

lem. One study found that 94% of hospitals experienced data breaches between the years 2010 and 2012.[1] In California alone, the Department received an estimated 8,400 reported breaches between January 1, 2016 and December 31, 2017. These proposed regulations clarify how the Department will enforce the Code.

Problem Statement

The Department, in its efforts to assess administrative penalties for breaches of patient medical information pursuant to the Code, requires regulations to establish a framework by which administrative penalties will be assessed in a fair and consistent manner, as well as to clarify reporting requirements for the health care facilities.

Objectives (Goals) of the Regulation

Broad objectives of this proposed regulatory action are:

- Fewer breaches of patient medical information.
- Increased vigilance by health care facilities to protect patient medical information.
- Closer alignment of state and federal law relating to patient medical information breaches.
- Improved patient experiences for the people of California.

Anticipated Benefits

- Increased security of patient medical information.
- Health care facilities will be more protective of patient medical information.
- Health care facilities will be more efficient in their internal data protection processes due to federal and state alignment.
- Health care facilities will be more efficient in responding to breaches due to federal and state alignment.
- Increased consumer confidence in the security of medical information.
- Increased transparency and consistency in calculation of assessed penalties.

EVALUATION AS TO WHETHER THE PROPOSED REGULATIONS ARE INCONSISTENT OR INCOMPATIBLE WITH EXISTING STATE AND FEDERAL REGULATIONS

The Department has determined that the proposed regulations are compatible and consistent with existing state and federal laws. Under the Health Insurance Portability and Accountability Act (HIPAA), the federal government has established provisions relating to medical information breaches. In drafting these proposed regulations, the Department has extensively used the HIPAA regulations as a model for developing its own. However, in some cases the HIPAA provisions differ from the final regulations proposed herein. These differences are often the result of variation between existing state and federal law as they relate to privacy and medical information (i.e. differences between underlying statutorily defined terms). In other cases, the Department has modeled its regulations after HIPAA regulations, but constructed them differently when the Department finds such changes are in the best interest of the people of California. HIPAA's provisions are meant to be a "floor" for patient protection standards, and a state may enact its own laws and regulations under certain circumstances, including, but not limited to, when the state's law provides greater protection. (45 C.F.R. §§ 160.201−205 (2013).) Therefore, the Department concludes that the proposed regulations are consistent with existing state and federal laws.

FORMS INCORPORATED BY REFERENCE

None.

MANDATED BY FEDERAL LAW OR REGULATIONS

Not applicable.

OTHER STATUTORY REQUIREMENTS

Not applicable.

LOCAL MANDATE

The Department has determined that this regulatory 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.

DISCLOSURES REGARDING THE PROPOSED ACTION

FISCAL IMPACT ESTIMATES

A) Cost to any local agencies or school districts that must be reimbursed pursuant to Section 17561 of Government Code:

The proposed regulations do not impose costs on any local agency or school district for which

[1] Ponemon Institute LLC, Third Annual Benchmark Study on Patient Privacy & Data Security, December 2012

reimbursement would be required pursuant to part 7 (commencing with section 17500) of division 4 of the Government Code.

B) The cost or savings to any state agency:

The Department estimates that the overall effect will be cost−neutral as affected regulated entities are already paying the financial penalties as appropriate under existing statutes. State operated facilities may receive fines if they fail to comply with patient medical information requirements.

C) Impact on any cost or savings in federal funding of the program:

There is no federal funding affected by the proposed regulatory action.

D) Other nondiscretionary costs or savings imposed on local agencies:

The proposed regulations do not impose other nondiscretionary costs or savings on any local agencies.

HOUSING COSTS

The Department has determined that the regulations will not have an impact on housing costs.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE

The Department has made an initial determination that these regulations would not have a significant statewide adverse economic impact directly affecting businesses, and individuals, including the ability of California businesses to compete with businesses in other states.

STATEMENT OF THE RESULTS OF THE ECONOMIC IMPACT ASSESSMENT

The Department has made an initial determination that these regulations would not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. The proposed regulations would not significantly affect:

- The creation or elimination of jobs within the state because the Department estimates that the regulation's financial impact would be cost−neutral and affected regulated entities are already paying the financial penalties as appropriate under existing statutes.
- The creation of new businesses or the elimination of existing businesses within the state because the Department estimates that the regulation's financial impact would be cost−neutral and both existing and potential new businesses would pay similar financial penalties as appropriate under existing statutes.
- The expansion of businesses currently doing business within the state because the Department estimates that the regulation's financial impact would be cost−neutral and affected regulated entities are already paying the financial penalties as appropriate under existing statutes.
- The regulatory action protect the patient's privacy rights regarding disclosures of medical information. Maintain security standards to prevent breaches which creates a positive impact to the health, safety and welfare of California. Also, the economy is not impacted because the Department estimates that cost is neutral as affected regulated entities are already paying the financial penalties as appropriate under existing statutes.

COST IMPACTS ON REPRESENTATIVE PERSON OR BUSINESS

The Department is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

BUSINESS REPORTING REQUIREMENT

The proposed regulations require health care facilities to report to the Department details regarding unlawful or unauthorized access to patients' medical information. The Department has found that this is necessary for the health, safety, and welfare of the people of the state.

EFFECT ON SMALL BUSINESS

Small businesses will be legally required to comply with the regulation and may incur a financial penalty from the enforcement of the regulation. Depending on the type and frequency of the information breach, a penalty would vary from no cost to a potentially substantial cost. However, the proposed regulation has a mechanism to adjust costs for facilities for which penalties are a burden.

SPECIFIC TECHNOLOGIES OR EQUIPMENT

This regulation does not mandate the use of specific technologies or equipment.

ALTERNATIVES CONSIDERED

In accordance with Government Code section 11346.5, subdivision (a)(13), the Department has determined that no reasonable alternative it considered or that has otherwise been identified and brought to the attention of the agency would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed action or would be more cost−effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The Department invites interested persons to present statements or arguments with respect to the proposed regulations at the scheduled hearing or during the written comment period.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDIES, REPORTS OR DOCUMENTS RELIED UPON

- Ponemon Inst., Third Annual Benchmark Study on Patient Privacy & Data Security (December 2012).
- Redspin, Inc., Breach Report 2013: Protected Health Information (PHI) (February 2014).
- The Health Insurance Portability and Accountability Act of 1996 (Pub.L. 104−191, 110 Stat. 1936, enacted August 21, 1996), Parts 160 and 164.
- Federal Register vol 78, no. 17, Jan. 25, 2013 (Part II).
- Cal. Reg. Notice Register 2012, No. 43−Z, p. 1564.
- *California Assn. of Health Facilities v. Department of Health Services* (1997) 16 Cal.4th 284 [65 Cal.Rptr.2d 872].
- *Eisenhower Medical Center v. Superior Court of Riverside County* (2014) 226 Cal. App. 4th 430 [172 Cal.Rptr.3d 165].

CONTACT PERSON

Inquiries regarding the substance of the proposed regulations described in this notice may be directed to Krisheidy Guerrero, email krisheidy.guerrero@cdph.ca.gov, phone (916) 327−0643. All other inquiries concerning the action described in this notice may be directed to Hannah Strom−Martin, Office of Regulations, at (916)440−7371, email hannah.strom−martin@cdph.ca.gov, or to the designated backup contact, Christy Correa, at (916) 440−7764, email christy.correa@cdph.ca.gov.

AVAILABILITY STATEMENTS

The Department has prepared and has available for public review an initial statement of reasons for the proposed regulations, all the information upon which the proposed regulations are based, and the text of the proposed regulations. The Office of Regulations, at the address previously noted, will be the location of public records, including reports, documentation, and other material related to the proposed regulations.

In order to request that a copy of this public notice, the regulation text, and the initial statement of reasons or alternate formats for these documents be mailed to you, please call (916) 440−7371 (or the California Relay Service at 711), or send an email to regulations@cdph.ca.gov, or write to the Office of Regulations at the address previously noted. Upon specific request, these documents will be made available in Braille, large print, audiocassette, or computer disk.

The full text of any regulation which is changed or modified from the express terms of the proposed action will be made available by the Department's Office of Regulations at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

A copy of the final statement of reasons when prepared will be available upon request from the Office of Regulations.

INTERNET ACCESS

Materials regarding the action described in this notice (including this public notice, the text of the proposed regulations, and the initial statement of reasons) that are available via the Internet may be accessed at www.cdph.ca.gov and by clicking on the following: Programs, Office of Regulations, and the Proposed Regulations link.

GENERAL PUBLIC INTEREST

DEPARTMENT OF FISH AND WILDLIFE

FISH AND GAME CODE SECTION 1653
CONSISTENCY DETERMINATION
REQUEST FOR
No Name Road Ford Replacement and
Fish Passage Improvement Project
(Tracking Number: 1653−2020−056−001−R4)
Monterey County

California Department of Fish and Wildlife (CDFW) received a Request to Approve on June 19, 2020, that the Resource Conservation District of Monterey County proposes to carry out a habitat restoration or enhancement project pursuant to Fish and Game Code section 1653. The proposed project involves removal and replacement of a concrete automobile ford that is currently limiting steelhead trout passage. The proposed project will be carried out on San Clemente Creek, located at 35425 Dormody Road, 11 miles south of Carmel Valley Village, Monterey County, California.

On March 30, 2020, the Central Coast Regional Water Quality Control Board (Regional Water Board) received a Notice of Intent (NOI) to comply with the terms of, and obtain coverage under, the General 401 Water Quality Certification Order for Small Habitat Restoration Projects (General 401 Order) for the No Name Road Ford Replacement and Fish Passage Improvement Project. The Regional Water Board determined that the Project, as described in the NOI, was categorically exempt from California Environmental Quality Act (CEQA) review (section 15333 — Small Habitat Restoration Projects) and met the eligibility requirements for coverage under the General 401 Order. The Regional Water Board issued a Notice of Applicability (WDID No. 32720WQ03;) for coverage under the General 401 Order on June 16, 2020.

The Resource Conservation District of Monterey County is requesting a determination that the project and associated documents are complete pursuant to Fish and Game Code section 1653 subdivision (d). If CDFW determines the project is complete, the District will not be required to obtain an incidental take permit under Fish and Game Code section 2081 subdivision (b) or a Lake or Streambed Alteration Agreement under Fish and Game Code section 1605 for the proposed project.

In accordance with Fish and Game Code section 1653 subdivision (e), if CDFW determines during the review, based on substantial evidence, that the request is not complete, the Resource Conservation District of Monterey County will have the opportunity to submit under Fish and Game Code section 1652.

DEPARTMENT OF TOXIC SUBSTANCES CONTROL

NOTICE OF PROPOSED SETTLEMENT

THIS NOTICE OF PROPOSED SETTLEMENT is published on July 3, 2020, for the property located at 12500 Lang Station Road in Canyon Country, Los Angeles County California (the "Site").

In accordance with Health and Safety Code sections 25100 et seq. (the Hazardous Waste Control Act), 25300 et seq. (the Hazardous Substance Account Act), 58009 and 58010, the Department of Toxic Substances Control ("DTSC") has authority to enter into agreements whereby DTSC covenants not to sue or assert claims for environmental remediation against prospective owners and certain long−term lessees of environmentally−impacted properties, if such agreements are sufficiently in the public interest.

Notice is hereby given that DTSC proposes to enter into an Agreement and Covenant Not to Sue, also known as a Prospective Purchaser Agreement ("PPA"), associated with the former Lubrication Company of America facility located at 12500 Lang Station Road in Canyon Country. The PPA would resolve certain potential claims of DTSC against the company that is the potential prospective owner of the Site. The potential prospective owner, Louis McCutcheon Inc. (LMI)

LMI intends to use the 4−acre site located at 12500 Lang Station Road in Canyon Country in Los Angeles County [Assessor's Parcel Numbers: 3210−017−0452]. LMI intends to use the site for outdoor storage of rubber−tired heavy equipment, certain types of railroad repair and construction materials, and possibly cargo containers. The PPA would resolve potential claims against LMI upon its potential acquisition of the Site and resulting change in status to owner.

Corrective action to address releases of hazardous wastes and hazardous constituents at the Site has been conducted by the State of California Department of Toxics. The potential purchaser agrees to cooperate fully with DTSC in its oversight of the environmental operations and maintenance (O&M) activities for response actions at the Site by other parties, and agrees to comply with the land use controls and to provide ongoing access to DTSC for the oversight of O&M activities of the Site.

The Prospective Purchaser Agreement is in the public interest because:

1. The beneficial reuse of the Site will allow for the potential employment of an estimated 35 construction−related jobs.
2. The project will generate approximately $1 million in annual property taxes and other revenue.

DTSC will hold a 30−day comment period on the above referenced PPA. Written comments on this proposed settlement must be submitted on or before 5:00 p.m., August 3, 2020. To ensure timely receipt by DTSC and LMI, you are requested to transmit your comments by overnight mail to:

Department of Toxic Substances Control
Attn: Jose Diaz
9211 Oakdale Avenue
Chatsworth, California 91311
Jose.Diaz@dtsc.ca.gov

Louis McCutcheon Inc.
Attn: Louis McCutcheon, President
11665 Broadway Road
Moorpark, California 93021
louismccutcheon@yahoo.com

If you have any questions regarding the Prospective Purchaser Agreement, or wish to obtain a copy, please call the DTSC contact identified above.

OCCUPATIONAL SAFETY AND HEALTH STANDARDS BOARD

NOTICE OF PUBLIC MEETING AND BUSINESS MEETING OF THE OCCUPATIONAL SAFETY AND HEALTH STANDARDS BOARD

Pursuant to Government Code Section 11346.4 and the provisions of Labor Code Sections 142.1, 142.2, 142.3, 142.4, and 144.6, the Occupational Safety and Health Standards Board of the State of California has set the time and place for a Public Meeting and Business Meeting:

PUBLIC MEETING:

On **August 20, 2020,** at 10:00 a.m. in the Auditorium of the State Resources Building
1416 9th Street, Sacramento, California.

At the Public Meeting, the Board will make time available to receive comments or proposals from interested persons on any item concerning occupational safety and health.

BUSINESS MEETING:

On **August 20, 2020,** at 10:00 a.m. in the Auditorium of the State Resources Building
1416 9th Street, Sacramento, California.

At the Business Meeting, the Board will conduct its monthly business.

DISABILITY ACCOMMODATION NOTICE: Disability accommodation is available upon request. Any person with a disability requiring an accommodation, auxiliary aid or service, or a modification of policies or procedures to ensure effective communication and access to the public hearings/meetings of the Occupational Safety and Health Standards Board should contact the Disability Accommodation Coordinator at (916) 274−5721 or the state−wide Disability Accommodation Coordinator at 1−866−326−1616 (toll free). The state−wide Coordinator can also be reached through the California Relay Service, by dialing 711 or 1−800−735−2929 (TTY) or 1−800−855−3000 (TTY−Spanish).

Accommodations can include modifications of policies or procedures or provision of auxiliary aids or services. Accommodations include, but are not limited to, an Assistive Listening System (ALS), a Computer−Aided Transcription System or Communication Access Realtime Translation (CART), a sign−language interpreter, documents in Braille, large print or on computer disk, and audio cassette recording. Accommodation requests should be made as soon as possible. Requests for an ALS or CART should be made no later than five (5) days before the hearing.

SUMMARY OF REGULATORY ACTIONS

REGULATIONS FILED WITH SECRETARY OF STATE

This Summary of Regulatory Actions lists regulations filed with the Secretary of State on the dates indicated. Copies of the regulations may be obtained by contacting the agency or from the Secretary of State, Archives, 1020 O Street, Sacramento, CA 95814, (916) 653−7715. Please have the agency name and the date filed (see below) when making a request.

File# 2020−0306−01
BOARD OF PHARMACY
Duty to Consult

In this regular rulemaking action the Board of Pharmacy amends one section to update consultation requirements consistent with Business and Professions

Code section 4112 and make additional stylistic changes.

Title 16
AMEND: 1707.2
Filed 06/19/2020
Effective 10/01/2020
Agency Contact: Lori Martinez (916) 574−7917

File# 2020−0505−02
CALIFORNIA ALTERNATIVE ENERGY AND ADVANCED TRANSPORTATION FINANCING AUTHORITY
Affordable Multifamily Energy Efficiency Financing Program

The California Alternative Energy and Advanced Transportation Financing Authority submitted this timely certificate of compliance action to make emergency−adopted regulations permanent that established the Affordable Multifamily Energy Efficiency Financing Program. The program provides affordable financing for owners of multifamily dwellings of five or more units to retrofit specified energy savings measures by providing credit enhancements to private finance and service entities.

Title 4
ADOPT: 10093.1, 10093.2, 10093.3, 10093.4, 10093.5, 10093.6, 10093.7, 10093.8, 10093.9, 10093.10, 10093.11
Filed 06/17/2020
Effective 06/17/2020
Agency Contact: Susan Mills (916) 651−3760

File# 2020−0605−02
DEPARTMENT OF EDUCATION
Conflict−of−Interest Code

This is a Conflict−of−Interest code that has been approved by the Fair Political Commission and is being submitted for filing with the Secretary of State and printing.

Title 5
AMEND: 70
Filed 06/23/2020
Effective 07/23/2020
Agency Contact: Patti Alverson (916) 319−0860

File# 2020−0507−01
DEPARTMENT OF INSURANCE
FAIR Plan Methodology to Calculate Insurer Credits

In these changes without a regulatory effect, the Department amends its regulation to make it consistent with the legislative changes made to Insurance Code section 10094.2. The amendment adds a category in which credit for premium writings do not need to be equally weighed.

Title 10
AMEND: 2590.1
Filed 06/18/2020
Agency Contact: Risa Salat−Kolm (415) 538−4127

File# 2020−0421−01
DEPARTMENT OF JUSTICE
Email update, deletion of inconsistent language, amend language

In these changes without regulatory effect, the Department of Justice (Department) proposes to amend several incorporated−by−reference forms which are used in the administration of the Supervision of Trustees and Fundraisers for Charitable Purposes Act. The Department proposes to remove language which is inconsistent with statute and to amend and clarify language so as to conform to a cross−referenced and amended Internal Revenue Service (IRS) form and to make more specific several references to information in an unamended portion of that IRS form.

Title 11
AMEND: 301, 303, 305, 308
Filed 06/22/2020
Agency Contact:
Angelise Marcigliano (916) 210−6066

File# 2020−0521−04
DEPARTMENT OF JUSTICE
Ammunition Vendor Licensing

The Department of Justice (Department) proposed this action to amend two regulations to clarify when ammunition vendor licensees are required to submit copies of renewed permits and licenses from local, state, and federal agencies, to establish the requirement to maintain an active Department−issued certificate of eligibility, and to make nonsubstantive changes to numbering.

Title 11
AMEND: 4261, 4263
Filed 06/22/2020
Effective 10/01/2020
Agency Contact:
Angelise Marcigliano (916) 210−6066

File# 2020−0512−02
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT
Proposition 65 — Chlorpyrifos MADLs

This action adopts three maximum allowable dose levels (MADLs) for chlorpyrifos under Proposition 65.

Title 27
AMEND: 25805
Filed 06/24/2020
Effective 10/01/2020
Agency Contact: Monet Vela (916) 323−2517

File# 2020−0610−01
OFFICE OF STATEWIDE HEALTH PLANNING AND DEVELOPMENT
Correcting Cross−References Update

The Office of Statewide Health Planning and Development submitted this action proposing changes without regulatory effect, pursuant to California Code of Regulations, title 1, section 100, to update cross−references in four regulations. The updated cross−references are based on a change in a statute or a change in a regulation.

Title 22
AMEND: 90417, 97212, 97213, 97221
Filed 06/22/2020
Agency Contact:
Kimberly Gustafson (916) 326−3939

File# 2020−0616−01
SECRETARY OF STATE
Vote−by−Mail Ballot Drop Boxes and Vote−by−Mail Drop−Off Locations

This emergency action by the Secretary of State extends the time in which ballots must be retrieved from unstaffed vote−by−mail drop boxes from 24 hours to 48 hours.

Title 2
AMEND: 20136
Filed 06/24/2020
Effective 06/24/2020
Agency Contact: Raj Bathla (916) 695−1597

PRIOR REGULATORY DECISIONS AND CCR CHANGES FILED WITH THE SECRETARY OF STATE

A quarterly index of regulatory decisions by the Office of Administrative Law (OAL) is provided in the California Regulatory Notice Register in the volume published by the second Friday in January, April, July, and October following the end of the preceding quarter. For additional information on actions taken by OAL, please visit www.oal.ca.gov.