DEPARTMENT OF CONSUMER AFFAIRS TITLE 16. BOARD OF PHARMACY

NOTICE OF PROPOSED REGULATORY ACTION CONCERNING: Digital Signatures

NOTICE IS HEREBY GIVEN that the California State Board of Pharmacy (Board) proposes taking the rulemaking action described under the heading Informative Digest/Policy Statement Overview below, after considering all comments, objections, and recommendations regarding the proposed action.

PUBLIC HEARING

The Board has not scheduled a public hearing on this proposed action. However, the Board will hold a hearing if it receives a written request for a public hearing from any interested person, or that person's authorized representative, no later than 15 days prior to the close of the written comment period. A hearing may be requested by making such request in writing addressed to the individuals listed under "Contact Persons" in this notice.

WRITTEN COMMENT PERIOD

Written comments relevant to the action proposed, 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 no later than Monday, February 3, 2025, or must be received by the Board at the hearing, should one be scheduled.

<u>Authority and Reference</u>: Pursuant to the authority vested by Business and Professions Code (BPC) section 4005 and Government Code (GC) section 16.5, the Board proposes adding section 1700 to Division 17 of Title 16 of the California Code of Regulations (CCR).

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

The Board is a state agency vested with the authority to license and regulate the pharmacy industry, including pharmacies, pharmacists, and pharmacy technicians (BPC section 4000, et seq.). The Board's mandate and mission are to protect the public (BPC section 4001.1).

Government Code section 16.5 establishes the authority for government agencies to accept digital signatures that meet specified conditions, including that each digital signature is unique to the person, capable of verification, under the sole control of the person using it, and linked to data in such a manner that if the data are changed, the digital signature is invalidated, and that it conforms to regulations adopted by the Secretary of State.

Existing regulation at Title 2, CCR section 22003 specifies acceptable technologies for use and acceptance of digital signatures—among the acceptable technologies is Public Key Cryptography. Public key cryptography is a method of encrypting or signing data.

Some programs using public key cryptography include DocuSign and Adobe Sign.

In April 2023, the Board issued a policy statement regarding the acceptance of digital signatures. To fully implement that policy statement, the Board must promulgate regulations. This proposal will add section 1700 to Article 1 of Division 17 of Title 16 of the CCR to establish the requirements for the use of digital signatures on documents submitted to the Board by the public.

Anticipated Benefits of Proposal

Protection of the public is the Board's highest priority in exercising its licensing, regulatory, and disciplinary functions. The Board has determined that this regulatory proposal will have the following benefits to the health and welfare of California residents.

This proposal specifies the requirements for the use of digital signatures on documents, written communication, and applications submitted to the Board. Accepting digital signatures is a benefit to the consumers of California, as it eases some of the current challenges licensees and applicants experience regarding signature requirements. Easing the signature requirements through the use of digital signatures will help reduce a barrier to licensure, in that wet signatures can take time to obtain, so use of digital signatures will reduce the time it takes for a complete application to be received by the Board. This will increase the number of licensed pharmacists, pharmacy technicians, pharmacies, and other Board licensees available to serve California consumers, thereby benefitting the health and welfare of California consumers.

This regulatory proposal does not affect employee safety or the state's environment.

Evaluation of Consistency and Compatibility with Existing State Regulations

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

DISCLOSURES REGARDING THIS PROPOSED ACTION

FISCAL IMPACT ESTIMATES

<u>Fiscal Impact on Public Agencies Including Costs/Savings to State Agencies or Costs/Savings in Federal Funding to the State:</u> The proposed regulation does not result in a fiscal impact to the state.

The proposed regulation does not result in a fiscal impact to the state in the form of federal funding or any cost or savings to any state agency.

Additionally, the Board does not anticipate additional workload or costs resulting from the proposed regulation.

Nondiscretionary Costs/Savings to Local Agencies: None

Cost to any Local Agency or School District for which Government Code Sections 17500 - 17630 Require Reimbursement: None

Mandate Imposed on Local Agencies or School Districts: None

Significant Effect on Housing Costs: None

Business Impact Estimates:

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.

The proposed regulation specifies the requirements for the use of digital signatures on applications, documents, and written communication submitted to the Board by the public. This regulation will benefit licensees and consumers, and will not have any adverse effects.

<u>Cost Impact on Representative Private Person or Business:</u>

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

RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS:

Impact on Jobs/New Businesses:

The Board concludes that this proposal will not:

- (1) create jobs within California;
- (2) eliminate jobs within California;
- (3) create new businesses within California;
- (4) eliminate existing businesses within California; and
- (5) expand businesses currently doing business in the State of California.

Benefits of Regulation:

The Board determined that this proposal will not create or eliminate jobs or businesses. The proposal specifies the requirements for use of digital signatures on documents, written communication, and applications that are submitted to the Board. Accepting digital signatures is a benefit to the consumers of California, as it eases some of the current challenges licensees and applicants experience specifically regarding signature requirements. This will increase the number of licensed pharmacists, pharmacy technicians, pharmacies, and other Board licensees available to serve California consumers, thereby benefitting the health and welfare of California consumers.

This regulatory proposal does not affect employee safety or the state's environment.

Business Reporting Requirements

This regulatory proposal does not require businesses to file a report with the Board.

Effect on Small Business:

While the Board does not have, nor does it maintain, data to determine if any of its licensees (pharmacies and clinics) are a "small business," as defined in Government Code section 11342.610, the Board has determined that the proposed regulatory action concerning the use of digital signatures on applications, documents, and written communication submitted to the Board is a benefit to businesses, including small businesses, and will not have an adverse effect.

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code section 11346.5(a)(13), the Board must determine that no reasonable alternative it considered, or that has otherwise been identified and brought to its attention, 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.

Any interested person may submit comments—relevant to the above determinations—in writing, at the address listed below for the <u>Contact Persons</u>, during the written comment period, or at the hearing if one is scheduled or requested.

AVAILABILITY OF INITIAL STATEMENT OF REASONS AND RULEMAKING FILE

The Board has compiled a record for this regulatory action, which includes the Initial Statement of Reasons (ISOR), proposed regulatory text, and all the information upon which the proposal is based. This material is contained in the rulemaking file and is available for public inspection upon request to the contact persons named in this notice.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations, 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/laws_regs/pending_regs.shtml.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

After considering all timely and relevant comments, the Board, upon its own motion or at the request of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals 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, with the modifications clearly indicated, will be available for review and written comment for 15 days prior to its adoption from the persons designated in this Notice as the Contact Persons and will be mailed to those persons who submit written comments or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

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 request to the Contact Person named below or by accessing the website listed below.

Contact Persons

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

Name: Lori Martinez

Address: Board of Pharmacy

2720 Gateway Oaks Drive, Ste. 100

Sacramento, CA 95833

Phone No.: (916) 518-3100 Fax No.: (916) 574-8618

E-Mail Address: PharmacyRulemaking@dca.ca.gov

The backup contact person is:

Name: Julie Ansel

Address: Board of Pharmacy

2720 Gateway Oaks Drive, Ste. 100

Sacramento, CA 95833

Phone No.: (916) 518-3100 Fax No.: (916) 574-8618

E-Mail Address: PharmacyRulemaking@dca.ca.gov

AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of the Notice of Proposed Action, the Initial Statement of Reasons, and the text of the regulations with modifications noted, as well as the Final Statement of Reasons when completed, and modified text, if any, can be accessed through the Board of Pharmacy's website at: https://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml.