

**TITLE 16. BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS**

INITIAL STATEMENT OF REASONS

Hearing Date: No hearing scheduled.

Subject Matter of Proposed Regulation: Digital Signatures

Section Affected: Add Title 16, California Code of Regulations (CCR) section 1700

Background and Statement of the Problem

The California State Board of Pharmacy (Board) is a state agency vested with the authority to license and regulate the pharmacy industry, including pharmacies, pharmacists, and pharmacy technicians (Business and Profession Code (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 from this regulatory action:

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 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 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.

Specific purpose of, and rationale for, proposed changes

The Board's proposal makes the following changes:

Section 1700 is added and reads:

Consistent with the authority established in Government Code Section 16.5, in any written communication, application or other document in which a signature is required or used, the Board shall accept digital signatures that meet the requirements set forth in the California Code of Regulations, Title 2, section 22003(a).

The purpose of adding this paragraph is to establish the specific requirements for digital signatures within the Board's regulations. The requirements for digital signatures are generally established within Government Code section 16.5 and Title 2, CCR section 22003(a). However, this addition is necessary to establish the specific requirements within the Board's regulations in order to provide clarity to the regulated public regarding the exact technology to use and the specific requirements for the digital signatures that the Board can accept.

The note is added to include the authority and reference cited as section 16.5 of the Government Code, as required.

Underlying Data

1. Relevant Meeting Materials and Minutes from the Licensing Committee Meeting held April 5, 2023 (Meeting Materials Agenda Item VI, Meeting Minutes)
2. Relevant Meeting Materials and Minutes from Board Meeting held April 19-20, 2023 (Meeting Materials Agenda Item XV(c), Meeting Minutes)
3. Relevant Meeting Materials and Minutes from Board Meeting held April 24-25, 2024 (Meeting Materials Agenda Item XIV(b), Meeting Minutes)

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.

The proposed amendment specifies the requirements for the use of digital signatures on applications, documents, and written communication submitted to the Board by the public. This is a benefit to the programs and not an adverse effect.

Economic Impact Assessment

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.

The Board determined that this proposal will not create or eliminate jobs or businesses. This proposal specifies the requirements for the 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 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.

Specific Technologies or Equipment

This regulation mandates the use of specific technologies or equipment, specifically, Public Key Cryptography. This mandate is necessary as the technology is required by the California Secretary of State regulations, as Government Code section 16.5 requires that digital signature acceptance conform to the regulations adopted by the Secretary of State.

Consideration of Alternatives

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific. The Board considered not adopting the proposed regulation; however, the Board determined that alternative was not reasonable, as specifying the requirements for digital signatures within the Board's regulations ensure clarity to the regulated public about the exact technology to use and the standards for digital signatures, which are established within other areas of State law.