TITLE 16. BOARD OF PHARMACY

NOTICE IS HEREBY GIVEN that the Board of Pharmacy is proposing to take the action described in the Informative Digest. 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 of Pharmacy at its office not later than 5:00 p.m. on June 20, 2011.

The board does not intend to hold a hearing in this matter. If any interested party wishes that a hearing be held, he or she must make the request in writing to the board. The request must be received in the board office not later than 15 days before the close of the written comment period.

The Board of Pharmacy, upon its own motion or at the instance 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 will be available for 15 days prior to its adoption from the person designated in this Notice as 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. Pursuant to the authority vested by Section 4005 of the Business and Professions Code, and to implement, interpret or make specific Sections 851 and 4005 of the Business and Professions Code, the Board of Pharmacy is proposing to add section 1727.2. and to amend section 1728 of Division 17 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

The Board of Pharmacy proposes to add Section 1727.2. to Article 3 of Division 17 of Title 16 of the California Code of Regulations for the purpose of requiring an applicant for a Pharmacist Intern license to submit to the board with his or her application a sealed, original Self-Query Report from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB). Business and Professions Code section 4207 specifies that the board shall make a thorough investigation to determine whether an applicant is qualified for the license being sought. Existing law does not require an applicant for an Intern pharmacist license to submit an original Self-Query Report from the NPDB-HIPDB; this proposal would make it a condition of licensure for an applicant for an Intern pharmacist license to submit the Self-Query Report with his or her application, as specified. The board has determined that the requirement to submit a Self Query Report, as specified in the proposal, is necessary and pertinent to the board’s investigation and will facilitate the board’s investigation to determine if a Pharmacist Intern applicant has been the subject of discipline in another state prior to making a license decision to grant or deny a license. This proposal is necessary to place an applicant of the requirement to submit a Self-Query Report with his or her application.
Existing regulation in subdivision (a) of Section 1728 specifies requirements for applicants who are seeking board authorization to take the Pharmacist licensure examination. This subdivision requires the applicant to submit to the board proof related to hours of pharmacy practice experience; satisfactory proof of the applicant’s graduation from a recognized school of pharmacy; fingerprints; and a signed copy of the examination security acknowledgement.

This proposed regulation would also require an applicant who is seeking board authorization to take the pharmacist licensure examination to submit to the board with his or her application a sealed, original Self-Query Report from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB). Existing law does not require an applicant seeking board authorization to take the pharmacist licensure examination to submit an original Self-Query Report from the NPDB-HIPDB; this proposal would make this a requirement and condition for such an applicant. Business and Professions Code section 4207 specifies that the board shall make a thorough investigation to determine whether an applicant is qualified for the license being sought. The board has determined that the requirement to submit a Self-Query Report, as specified in the proposal, is necessary and pertinent to the board’s investigation and will facilitate the board’s investigation to determine if an applicant to take the pharmacist licensure examination has been the subject of discipline in another state prior to making a license decision on his or her application. This proposal is necessary to place the applicant on notice of the requirement to submit a Self-Query Report with his or her application.

**FISCAL IMPACT ESTIMATES**

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

*Non-discretionary 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 businesses, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the fact that the proposed regulation does not affect a business; rather, it affects applicants (individuals) who are seeking licensure from the Board of Pharmacy.

*Impact on Jobs/New Businesses:* The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the creation of new or elimination of existing jobs businesses or the expansion of businesses in the State of California.
**Cost Impact on Representative Private Person or Business:** The agency is not aware of any cost impacts that a representative business would necessarily incur in reasonable compliance with the proposed action.

For an applicant applying for authorization to take the pharmacist licensure exam, the board estimates that a representative private person presently incurs approximately $253 in reasonable compliance with the existing regulation. The board estimates that a representative private person may incur additional costs of approximately $28 in reasonable compliance with the proposed action. The board based this estimate on the following information and/or assumptions:

**Estimate of Current Costs:**
- Application Fee to take Exam: $200.00
- Fingerprint Fees: $51.00
- Paper, Envelope, Postage: $2.00

**TOTAL:** $253.00

**Estimate of Additional Costs:**
- NPDB Self-Query: $8.00
- HIPDB Self-Query: $8.00
- Paper, Envelope, Postage: $2.00
- Notary Fee: $10.00

**TOTAL:** $28.00

For an applicant for licensure as an Intern Pharmacist, the board estimates that a private person presently incurs approximately $143 in reasonable compliance with the existing regulation. The board estimates that a representative private person may incur additional costs of approximately $28 in reasonable compliance with the proposed action. The board based this estimate on the following information and/or assumptions:

**Estimate of Current Costs:**
- Application Fee to take Exam: $90.00
- Fingerprint Fees: $51.00
- Paper, Envelope, Postage: $2.00

**TOTAL:** $143.00

**Estimate of Additional Costs:**
- NPDB Self-Query: $8.00
- HIPDB Self-Query: $8.00
- Paper, Envelope, Postage: $2.00
- Notary Fee: $10.00

**TOTAL:** $28.00

**Effect on Housing Costs:** None
EFFECT ON SMALL BUSINESS

The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the fact that the proposed regulation does not affect a business; rather, it affects applicants (individuals) who are seeking licensure from the Board of Pharmacy.

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy 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 or would be as effective and less burdensome to affected private persons than the proposal described in this Notice.

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

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy 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 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 1625 N. Market Blvd., N219, Sacramento, California 95834, or from the Board of Pharmacy’s Web site 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 request to the contact person named below or by accessing the Board of Pharmacy’s Web site (www.pharmacy.ca.gov).
CONTACT PERSON

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

Name: Carolyn Klein
Address: 1625 N. Market Blvd., N219
         Sacramento, CA 95834
Telephone No.: (916) 574-7913
Fax No.: (916) 574-8618
E-Mail Address: Carolyn.Klein@dca.ca.gov

The backup contact person is:

Name: Anne Sodergren
Address: 1625 N. Market Blvd., N219
         Sacramento, CA 95834
Telephone No.: (916) 574-7910
Fax No.: (916) 574-8618
E-Mail Address: Anne.Sodergren@dca.ca.gov

Website Access. Materials regarding this proposal can be found at www.pharmacy.ca.gov.