

# **Joint Commission on Health Care**

## **Pharmacist – Regulation Legislation House Bills 1961 and 1966 (Del. Rust)**

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### **2011 Legislation Addressing Board of Pharmacy Regulations**

- ▶ The Chairman of the House Committee on Health, Welfare and Institutions (HWI) asked JCHC to review the provisions of HB 1961 and HB 1966 (Delegate Rust) which were left in HWI.
  - The bills seek to address issues brought to Delegate Rust's attention by a constituent whose infant child was given an overdose of a prescription medication because the prescription bottle was mislabeled.
    - As of now, it appears the child will suffer no permanent/long-term harm.

## Statement of Issue

- ▶ The constituent filed a complaint with the Board of Pharmacy.
  - The case took over a year to be resolved.
  - Because no disciplinary action was taken, the constituent was not certain whether a conflict of interest played a role in the outcome of the case.

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## House Bill 1961

- ▶ Would have required the Board of Pharmacy “to promulgate regulations including the criteria for recusal of individual Board members from participation in any disciplinary proceeding involving a pharmacy, pharmacist or pharmacy technician with whom the Board member works, or by whom the member is employed.”

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## **HWI Committee Questions Regarding HB 1961**

1. Is the legislation needed?
2. Should the legislation be broader to include all regulated professions?
3. Should the relationship between the subject of the hearing and the Board member be better defined?
4. Should there be penalties for not disclosing any such relationship?
5. Should there be penalties for not recusing oneself from the proceeding involving where the member is employed?
6. Any other matters the Commission feels should be addressed.

Source: March 10, 2011 Letter from Delegate Orrock to Delegate Cline.

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## **Is the legislation needed?**

- ▶ A 2011 Survey of Pharmacy Law, assembled by the National Association of Boards of Pharmacy, found that no state required Board-member recusal/disqualification/exclusion based on the member being employed by the same pharmacy or otherwise working with the individual against whom a complaint had been filed.
- ▶ In fact, only Virginia and Louisiana have any language involving recusal in statute.

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## Current Law/Practice

- ▶ Virginia Code § 54.1-110B states,
  - “A board member shall disqualify himself and withdraw from any case in which he cannot accord fair and impartial consideration. Any party may request the disqualification of any board member by stating with particularity the grounds upon which it is claimed that fair and impartial consideration cannot be accorded. The remaining members of the board or panel shall determine whether the individual should be disqualified.”
- Applies to all regulatory boards.

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## Louisiana's Recusal Provisions

- ▶ A Board member may be **recused**:
  - By his own motion because of an inability to contribute to a fair and impartial hearing or,
  - By a majority vote of the board members present based on the following grounds:
    - prejudicial or personal interest in a case that might prevent one from participating in an impartial hearing;
    - the presiding administrative hearing officer may recuse himself on his own motion or he may be disqualified based upon his own inability to contribute to or conduct an impartial hearing by the respondent filing an affidavit of specific grounds at least five days prior to the scheduled hearing.

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## **How Do Board Members Address Conflicts?**

- ▶ The process for resolving conflicts, as well as the framework of the disciplinary/complaint process is basically the same for all professions under the Department of Health Professions.
  - However, since HB 1961 focused on the Board of Pharmacy, to the extent possible we restricted our review to the Board of Pharmacy and its laws and regulations.

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## **How Do Board Members Address Conflicts?**

- ▶ The current disciplinary process for pharmacists includes several opportunities for the Board staff and members to identify potential conflicts of interest.
  - First, when a case is initially sent to the Board for a probable cause determination, Board staff identify obvious conflicts of interest and exclude those Board members from any involvement with that case.
  - Second, if there is need for further probable cause review, the case is presented to a committee of the Board to determine if a violation of a law or regulation exists. At this time, such Board members have the opportunity to recuse themselves for any conflict of interest.

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## **How Do Board Members Address Conflicts?**

- ▶ The Board of Pharmacy indicates that the current system works. They indicate that board members:
  - Are trained during orientation on consideration of conflict of interest, which entails two parts:
    1. Whether the Board member has information that other Board members do not have and/or
    2. Whether the Board member can render a fair and impartial decision.

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## **How Do Board Members Address Conflicts?**

- ▶ The Board of Pharmacy indicated that members:
  - Routinely consult Board Counsel regarding potential conflicts.
  - Routinely disqualify themselves for a wide variety of reasons: neighbors, old friends, coach each others' kids, etc.
  - Tend to be overly cautious.
  - Have had very few complaints regarding conflict of interest and recusal submitted.

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## **How Do Board Members Address Conflicts?**

- ▶ In addition, the Board representatives indicated there is no clear line on when a conflict occurs, that the system works best when recusal is allowed on a case by case basis, and that more prescriptive language in statute would not be useful.
- ▶ Furthermore, considering there is little evidence to suggest conflict of interest/recusal is a problem, a legislative mandate and/or sanctions do not seem to be necessary at this time.

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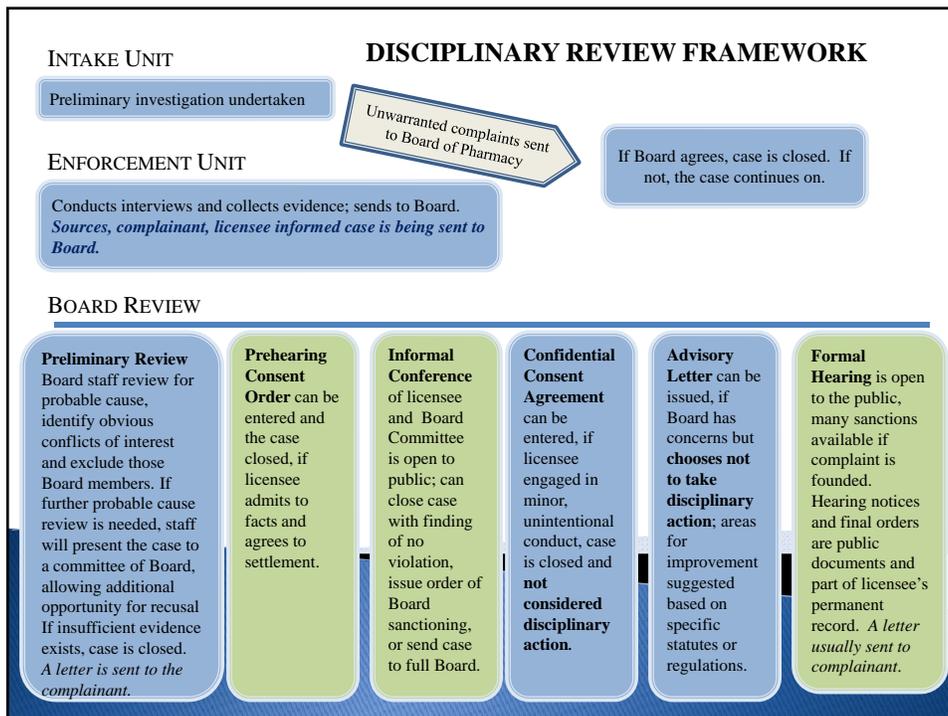
## **Conflicts of Interest and Recusals Could Be Documented**

- ▶ While the current process may work well, the Board of Pharmacy could improve its documentation by including in the minutes of any disciplinary proceeding, a statement regarding any recusal by a Board member from hearing the case. (Option 2).

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## What Information is Provided to Complainants?

- ▶ Complainants are afforded certain rights to be kept informed of Board actions within Title 54.1 of the *Code of Virginia*:
  - General information **must** be provided regarding “investigative and disciplinary procedures” of DHP. *Code* § 54.1-2400.2(F) (*Appendix 1*).
  - Specific information **may** be provided by the relevant board: (i) that an investigation has been conducted, (ii) that the matter was concluded without a disciplinary proceeding, (iii) of the process the board followed in making its determination, and (iv), if appropriate, that an advisory letter from the board has been communicated to the person who was the subject of the complaint or report.” *Code* § 54.1-2400.2(F) (*Appendix 2*)
  - Specific information for all **disciplinary actions must** be provided by the relevant board: “the date and location of any disciplinary proceeding, allegations against the respondent, and the list of statutes and regulations the respondent is alleged to have violated...[and] the disposition of a disciplinary case.”



## Final Actions

- ▶ All notices and final orders related to **disciplinary actions** are public documents and part of the licensee's permanent record.
  - Copies of final orders are *usually* mailed to the original complainant.
- ▶ All other information related to the disciplinary action is confidential.
- ▶ All decisions, including conflict of interest issues are appealable to the circuit court.

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## House Bill 1966

- ▶ HB 1966 would have allowed “anyone to report to the Board of Pharmacy any information on a pharmacist, pharmacy intern, or pharmacy technician who may have substance abuse or mental health issues that render him a danger to himself or others.”

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## HWI Committee Questions Regarding HB 1966

1. Is the legislation needed?
2. Should there be penalties for not reporting an impairment?
3. Any other matters the Commission feels should be addressed.

Source: March 10, 2011 Letter from Delegate Orrock to Delegate Cline.

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## Current Law/Practice

- ▶ Current law already allows any person to make a report to the Board of Pharmacy or the Department of Health Professions.
- ▶ *Code of Virginia* § 54.1-2400.8 of states that “any person
  - (i) making a report regarding the conduct or competency of a health care practitioner as required by law or regulation,
  - (ii) making a voluntary report to the appropriate regulatory board or to the Department of Health Professions regarding the unprofessional conduct or competency of any practitioner licensed, certified, or registered by a health regulatory board, or
  - (iii) providing information pursuant to an investigation or testifying in a judicial or administrative proceeding as a result of such reports shall be immune from any civil liability resulting therefrom unless such person acted in bad faith or with malicious intent.”

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## Informing the Public

- ▶ Additionally, *Code of Virginia* § 54.1-3314 requires every licensed pharmacist to display his license “conspicuously in the place in which he regularly practices.”
  - The displayed license also specifically states that “To provide information or file a complaint about a licensee...” and lists the Department of Health Professions telephone complaint number.

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## Some Reporting Requirements Do Not Apply to All Pharmacists

- ▶ Virginia Code § 54.1-2400.6
  - Requires hospitals and health care institutions to report on disciplinary actions taken against licensed, certified or registered health professionals including evidence that the “health professional is in need of treatment or has been committed or admitted as a patient...for treatment of substance abuse or a psychiatric illness that may render the health professional a danger to himself, the public or his patients.”
  - Applies to pharmacies within hospitals.
  - Grants immunity from liability.
  - Provides for a \$25,000 civil penalty for failure to report in the required time frame.

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## Legislative History on Reporting

- ▶ In 2008, the Board of Pharmacy voted to support legislation requiring mandatory reporting for pharmacies/pharmacists that mirrored the mandatory reporting requirements for hospitals.
  - The Board received public comment from the National Association of Chain Drug Stores opposing the legislative proposal; the comment stated, in part:
    - “A preferable approach...is to make reporting known and suspected problems *voluntary*, and to provide a safe harbor from board disciplinary actions if the licensee experiencing the problem voluntarily reports to the board and agrees to undergo treatment under the Virginia Department of Health’s Health Practitioners’ Intervention Program.”
  - Legislation was never introduced.

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## Policy Options

- ▶ **Option 1:** Send report findings to the Chairman of the House Committee on Health, Welfare and Institutions and take no further action.
- ▶ **Option 2:** Send report findings to the Chairman of the House Committee on Health, Welfare and Institutions and include in the letter that JCHC voted:
  - In support of recommending that the Board of Pharmacy record, in the minutes of any formal disciplinary hearing, a statement regarding any Board member who recused himself from participating in the hearing.

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## Policy Options

- ▶ **Option 3:** Send report findings to the Chairman of the House Committee on Health, Welfare and Institutions and include in the letter that JCHC voted:
  - In support of amending the *Code of Virginia* § 54.1-2400.2(F) to change the permissive “may” to a compulsory “shall” as shown:

“The relevant board may [*shall*] also inform the source of the complaint or report (i) that an investigation has been conducted, (ii) that the matter was concluded without a disciplinary proceeding, (iii) of the process the board followed in making its determination, and (iv) if appropriate, the result of the proceeding including that an advisory letter from the board has been communicated to the person who was the subject of the complaint or report without the content of the letter.”

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## Policy Options

- ▶ **Option 4:** Send report findings to the Chairman of the House Committee on Health, Welfare and Institutions and include in the letter that JCHC voted:
  - In support of amending Title 54 of the *Code of Virginia* to extend mandatory reporting requirements (similar to requirements for health care institutions) to require pharmacists and pharmacies to report on disciplinary actions, treatment needs, and commitments and inpatient admissions related to “substance abuse or psychiatric illness that may render the ...[pharmacy-related] professional a danger to himself, the public or his patients.”

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## Public Comment

- ▶ Written public comments on the proposed options may be submitted to JCHC by close of business on October 6, 2011.
- ▶ Comments may be submitted via:
  - E-mail: [jhoyle@jchc.virginia.gov](mailto:jhoyle@jchc.virginia.gov)
  - Fax: 804-786-5538
  - Mail: Joint Commission on Health Care  
P.O. Box 1322  
Richmond, Virginia 23218
- ▶ Comments will be summarized and reported during the October 17<sup>th</sup> meeting.

▶ Website – <http://jchc.virginia.gov>