

**REPORT OF THE  
JOINT COMMISSION ON HEALTH CARE**

**Consideration of Regulatory  
Changes for the Board of Pharmacy**

**TO THE GOVERNOR AND  
THE GENERAL ASSEMBLY OF VIRGINIA**



**REPORT DOCUMENT NO. 131**

**COMMONWEALTH OF VIRGINIA  
RICHMOND  
2012**



**Code of Virginia § 30-168.**

The Joint Commission on Health Care (the Commission) is established in the legislative branch of state government. The purpose of the Commission is to study, report and make recommendations on all areas of health care provision, regulation, insurance, liability, licensing, and delivery of services. In so doing, the Commission shall endeavor to ensure that the Commonwealth as provider, financier, and regulator adopts the most cost-effective and efficacious means of delivery of health care services so that the greatest number of Virginians receive quality health care. Further, the Commission shall encourage the development of uniform policies and services to ensure the availability of quality, affordable and accessible health services and provide a forum for continuing the review and study of programs and services.

The Commission may make recommendations and coordinate the proposals and recommendations of all commissions and agencies as to legislation affecting the provision and delivery of health care.

For the purposes of this chapter, "health care" shall include behavioral health care.

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**JCHC Staff**

Kim Snead

Executive Director

Stephen W. Bowman

Senior Staff Attorney/Methodologist

Michele L. Chesser, PhD

Senior Health Policy Analyst

Jaime H. Hoyle

Senior Staff Attorney/Health Policy Analyst

Sylvia A. Reid

Publication/Operations Manager



## Preface

This report, requested by the Chairman of the House Committee on Health, Welfare and Institutions, reviews the effect of statutory provisions contained in House Bills 1961 and 1966. The bills, which were left in committee, were introduced by Delegate Thomas Davis Rust to make the following changes:

- HB 1961 would require 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.”
- HB 1966 would allow “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.”

Joint Commission on Health Care (JCHC) staff reviewed the Board of Pharmacy’s disciplinary process and compared the relevant laws in Virginia to those in other states. With regard to recusal requirements, no state currently requires a regulatory board member to recuse or otherwise disqualify himself based on being employed by the same pharmacy as the subject of a complaint. The *Code of Virginia* § 54.1-110.B includes the general requirement for a member of any of the Boards within the Department of Health Professions to disqualify himself and “withdraw from any case in which he cannot accord fair and impartial consideration.”

With regard to reporting substance abuse or mental health problems, current State law in *Code of Virginia* § 54.1-2400.8 already allows any person to report to the Board of Pharmacy or Department of Health Professions on any health care practitioner regarding unprofessional conduct or competency with immunity “unless such person acted in bad faith or with malicious intent.”

Several policy options were presented for JCHC-member consideration. The option, to provide a written report to the Chairman of the House Committee on Health, Welfare and Institutions without making any recommendation or taking any other action, was approved.

On behalf of the Joint Commission, I would like to thank the individuals and organizations who assisted in this study including the Virginia Department of Health Professions, the Board of Pharmacy, and the Virginia Pharmacy Association.

Kim Snead  
Executive Director  
May 2012



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LETTER REQUESTING JCHC STUDY  
CHAIRMAN, HOUSE COMMITTEE ON HEALTH,  
WELFARE AND INSTITUTIONS

HOUSE BILLS 1966 & 1966 – 2011 SESSION  
Delegate Thomas Davis Rust





## Consideration of Regulatory Changes for the Board of Pharmacy

House Bills 1961 and 1966, which were left in the House Committee on Health, Welfare and Institutions, were referred to the Joint Commission on Health Care (JCHC) for further study by the House Committee Chairman.

HB 1961 and HB 1966 were introduced by Delegate Thomas Davis Rust to make the following changes:

- HB 1961 would require 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.”
- HB 1966 would allow “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.”

The bills sought to address issues brought to Delegate Rust’s attention by a constituent whose infant child was given a non-lethal overdose of a prescription medication because the prescription bottle was mislabeled. The constituent filed a complaint with the Board of Pharmacy, but because the complaint was resolved confidentially, the constituent was not informed regarding how the complaint was resolved.

### Required Recusal if Board Member Works for the Same Pharmacy (HB 1961)

The 2011 *Survey of Pharmacy Law*, compiled by the National Association of Boards of Pharmacy, found that no state required Board-member recusal, disqualification, or 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 had any language involving recusal in statute. *Code of Virginia* § 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.”

(Note that this language applies to all of the regulatory boards within the Virginia Department of Health Professions.)

Louisiana’s administrative regulations include recusal provisions of interest which state:

“A board member...may be recused by one’s own motion because of an inability to contribute to a fair and impartial hearing or may be recused by a majority vote of the board members present based on the...grounds [of] prejudicial or personal interest in a case that might prevent one from participating in an impartial hearing....”<sup>1</sup>

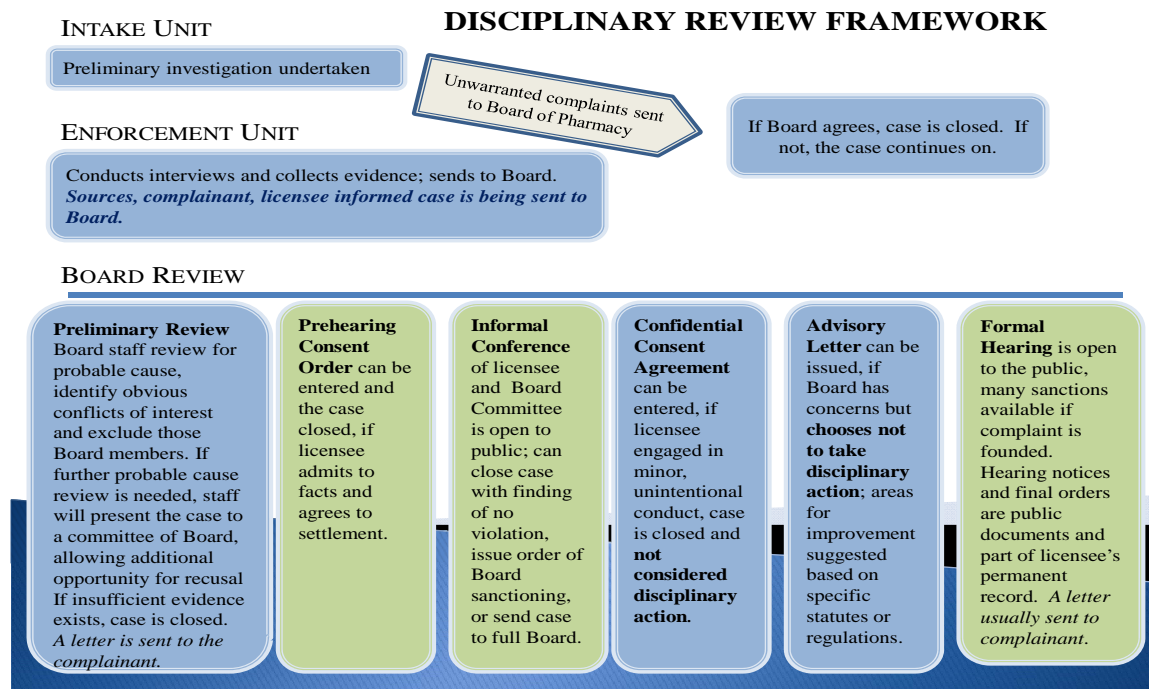
***Regulatory Hearings Include Opportunities for Board-Member Recusal.*** The disciplinary hearing process includes several opportunities for Board staff and members to identify potential

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<sup>1</sup> *Louisiana Administrative Code*, Title 46 § 317.A.1.

conflicts of interest. As shown in Figure 1, during the preliminary review for probable cause, staff determines whether any Board members have obvious conflicts of interest and if so, excludes those members from any involvement with the case. If the case is presented to a Board committee for further probable cause review, participating Board members will have an opportunity to recuse themselves for any conflict of interest.

Figure 1



Source: JCHC staff analysis.

Board of Pharmacy representatives indicated that the current system works well in guarding against potential conflicts of interest. During orientation, Board members receive training regarding conflict of interest considerations including determination of whether the Board member has information that other Board members do not have and/or whether the Board member can render a fair and impartial decision.

Pharmacy Board representatives also indicated 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.; and tend to be overly cautious in considering conflicts of interest. The Board has had very few complaints submitted regarding conflict of interest and recusal which they indicated would seem to suggest that conflict of interest/recusal is not a problem. Board representatives also stated that legislating this area of the

disciplinary process is difficult because there is no clear line on when a conflict occurs. The representatives noted that the system works best when recusal is allowed on a case by case basis. (Note that the framework for the disciplinary/complaint process is basically the same for all of the professions within the Virginia Department of Health Professions.<sup>2</sup>)

***Study Findings Regarding Conflict of Interest and Recusal.*** JCHC staff found that while the process for determining conflict of interest may work well, the Board of Pharmacy could improve its recusal documentation by including in the minutes of any disciplinary proceeding, a statement regarding any recusal by a Board member from hearing the case. Because much of the recusal process is confidential, a statement on the record regarding conflict of interest could add some transparency and indicate to the public that conflict of interest is being considered and addressed throughout the process.

Still, there is a requirement for some transparency within the disciplinary process. 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). 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). 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.”

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. However, all of the remaining information related to the disciplinary action is confidential. All decisions, including conflict of interest issues are appealable to the circuit court.

### **Reporting on Substance Abuse or Mental Health Issues (HB 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.”

Current law already allows any person to make a report to the Board of Pharmacy or to its parent agency, the Department of Health Professions. *Code of Virginia* § 54.1-2400.8 states “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

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<sup>2</sup> Since HB 1961 addresses statutory requirements for the Board of Pharmacy rather than for the Department of Health Professions, to the extent possible, staff limited this review to the Board of Pharmacy and its laws and regulations.

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.”

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

There are other reporting requirements that do not apply to all pharmacists. For instance, *Code of Virginia* § 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.” The *Code* section applies to pharmacies within hospitals, but not to other pharmacies. A civil penalty of \$25,000 may be assessed for failure to report in the required time frame and immunity from liability for reporting is provided.

In 2008, the Board of Pharmacy voted to support legislation requiring mandatory reporting for pharmacies and 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 to expand this type of mandatory reporting to pharmacies and pharmacists has not been introduced.

### **Policy Options and Public Comment**

Four policy options were presented for JCHC-member consideration and for public comment. Dr. Dianne Reynolds-Cane, Director of the Department of Health Professions, submitted the only comment, indicating uncertainty in how Option 2 would be implemented and opposition to Option 3 as written.

**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.

***Dr. Dianne Reynolds-Cane (DHP) commented:***

“We are uncertain about what sort of “statement” is contemplated. *If a board member recuses himself at a formal hearing (or an informal conference), the minutes of the meeting would already include that occurrence....* There are numerous scenarios surrounding the issue of recusal, so the Department has some

concerns as to whether there is an expectation about the ‘statement’ in the minutes apart from recording the fact of a member’s recusal at the formal hearing, which would already be captured in the minutes.”

**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.”

***Dr. Dianne Reynolds-Cane (DHP) commented in opposition to Option 3 as written:***

“While it is currently discretionary, boards within the Department already do provide the information enumerated in the Code in the letter that goes to a source of a complaint. However, it would be our preference for the boards to have *authorization* to share such information with a source but to retain the current permissive language.”

**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.”

***Subsequent Action by the Joint Commission on Health Care.*** Based on the study findings, Joint Commission members voted to send report findings to the Chairman of the House Committee on Health, Welfare and Institutions and take no further action.

**JCHC Staff for this Report**

Jaime H. Hoyle

Senior Staff Attorney/Health Policy Analyst



# Attachments





## **Joint Commission on Health Care**

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

September 19, 2011

**Jaime Hoyle**  
Senior Staff Attorney/Health Policy Analyst

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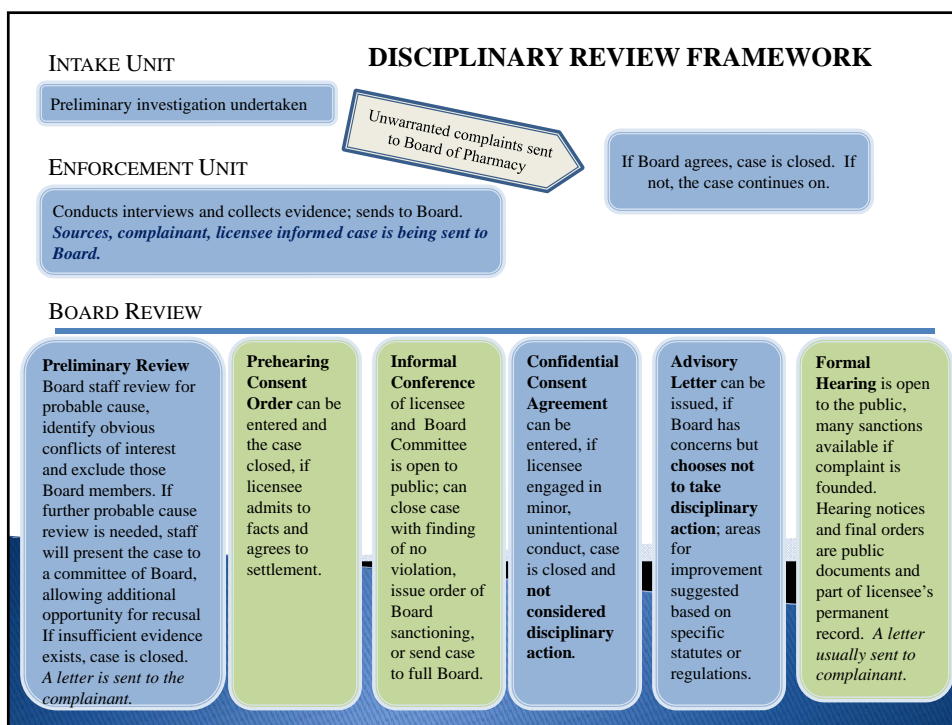
## **Conflicts of Interest and Recusals Could Be Documented**

- ▶ 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>



COMMONWEALTH OF VIRGINIA  
HOUSE OF DELEGATES  
RICHMOND

ROBERT D. "BOBBY" ORROCK  
POST OFFICE BOX 458  
THORNBURG, VIRGINIA 22565  
  
FIFTY-FOURTH DISTRICT

COMMITTEE ASSIGNMENTS:  
HEALTH, WELFARE AND INSTITUTIONS (CHAIRMAN)  
FINANCE  
AGRICULTURE, CHESAPEAKE AND  
NATURAL RESOURCES

March 10, 2011

Delegate Benjamin L. Cline, Chairman  
Joint Commission on Healthcare  
P. O. Box 1322  
Richmond, VA 23218

Dear Delegate Cline:

Two bills HB1961 and HB1966 were introduced by Delegate Rust in 2011 General Assembly session. Both bills were heard by a subcommittee of the Health Welfare and Institutions Committee. After hearing the bills, the subcommittee felt both bills needed additional study and input from the Joint Commission on Healthcare and, by this letter, I am requesting the Commission to do so.

HB1961: This bill would have required the recusal of a Board of Pharmacy member from participating in a disciplinary proceeding involving a person with whom the Board member works or by whom the member is employed. The issues which need to be addressed are as follows:

1. Is the legislation necessary?
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 a proceeding where the member is employed?
6. Any other matter the Commission feels should be addressed.

HB1966 (Amendment in Nature of a Substitute): This bill requires any medical practitioner who in his professional capacity becomes aware of an impaired practitioner to report to the Director of the Department of Health Professions such person. The issues which need to be addressed are as follows:

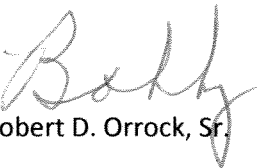
1. Is the legislation necessary?
2. Should there be penalties for not reporting an impairment?
3. Any other matter the Commission feels should be addressed.

Delegate Benjamin L. Cline  
Joint Commission on Healthcare  
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These matters were brought to Delegate Rust's attention by a constituent who was the victim of a prescription error with associated negative experiences and the above bills might reduce or prevent such occurrences in the future. The constituent has brought forward instances where recusals have not occurred when the professional board member participating in the disciplinary hearing was an employee of the same firm as the individual in the hearing. The constituent has volunteered to participate in the Commission work as a citizen representative. Her name is Sarah Tracy and she may be contacted at [slarson72@aim.com](mailto:slarson72@aim.com).

Thank you for our consideration of this request to study these matters. I would appreciate it if you could add this to the agenda for work this coming year.

Best regards,



Robert D. Orrock, Sr.



11102718D

HOUSE BILL NO. 1961

Offered January 12, 2011

Prefiled January 11, 2011

A BILL to amend and reenact § 54.1-3307 of the Code of Virginia, relating to recusal of Board of Pharmacy members from certain proceedings.

Patron—Rust

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3307 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3307. Specific powers and duties of Board.

A. The Board shall regulate the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding, or disposal of drugs and devices. The Board shall also control the character and standard of all drugs, cosmetics and devices within the Commonwealth, investigate all complaints as to the quality and strength of all drugs, cosmetics, and devices and take such action as may be necessary to prevent the manufacturing, dispensing, selling, distributing, processing, compounding and disposal of such drugs, cosmetics and devices that do not conform to the requirements of law.

The Board's regulations shall include criteria for:

1. Maintenance of the quality, quantity, integrity, safety and efficacy of drugs or devices distributed, dispensed or administered.

2. Compliance with the prescriber's instructions regarding the drug, its quantity, quality and directions for use.

3. Controls and safeguards against diversion of drugs or devices.

4. Maintenance of the integrity of, and public confidence in, the profession and improving the delivery of quality pharmaceutical services to the citizens of Virginia.

5. Maintenance of complete records of the nature, quantity or quality of drugs or substances distributed or dispensed, and of all transactions involving controlled substances or drugs or devices so as to provide adequate information to the patient, the practitioner or the Board.

6. Control of factors contributing to abuse of legitimately obtained drugs, devices, or controlled substances.

7. Promotion of scientific or technical advances in the practice of pharmacy and the manufacture and distribution of controlled drugs, devices or substances.

8. Impact on costs to the public and within the health care industry through the modification of mandatory practices and procedures not essential to meeting the criteria set out in subdivisions 1 through 7 of this section.

9. 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.

10. Such other factors as may be relevant to, and consistent with, the public health and safety and the cost of rendering pharmacy services.

B. The Board's regulations to implement the criteria set forth in subsection A shall include, but shall not be limited to, the establishment and implementation of a pedigree system, as defined in subsection D.

The Board shall structure the implementation of the pedigree with limited application to certain schedules or certain drugs, upon finding that such drugs are more subject to counterfeiting. In order to maintain a current and appropriate list of drugs susceptible to counterfeiting, the Board may amend such list in its regulations. Such amendments to the list shall be exempt from the requirements of Article 2 (§ 2.2-4006 et seq.) of the Administrative Process Act. The Board shall establish in regulation a process for amending such list that provides notice and opportunity for public comment. The Board shall limit the implementation of a pedigree system to those drugs that have left the normal distribution channel as defined in subsection D. The pedigree shall also satisfy the requirements of 21 U.S.C. § 353(e), regarding requirements for wholesale distributors of drugs in interstate commerce. The Board may provide for exceptions to the pedigree requirements of this section for emergency medical reasons as defined in regulation.

C. The Board may collect and examine specimens of drugs, devices and cosmetics that are manufactured, distributed, stored or dispensed in the Commonwealth.

D. For the purposes of this section:

INTRODUCED

HB1961

59 "Normal distribution channel" means a chain of custody for a prescription drug from initial sale by a  
60 pharmaceutical manufacturer, through acquisition and sale by one wholesale distributor as defined in  
61 § 54.1-3401, that is not exempted pursuant to § 54.1-3401.1, until sale to a pharmacy or other person  
62 dispensing or administering the controlled substance; or a chain of custody for a prescription drug from  
63 initial sale by a pharmaceutical manufacturer, through acquisition and sale by one wholesale distributor  
64 as defined in § 54.1-3401, that is not exempted pursuant to § 54.1-3401.1, to a chain pharmacy  
65 warehouse to its intracompany pharmacies; or a chain of custody for a prescription drug from initial sale  
66 by a pharmaceutical manufacturer to a chain pharmacy warehouse to its intracompany pharmacies.  
67 "Pedigree" means a paper document or electronic file recording each distribution of a controlled  
68 substance from sale by a pharmaceutical manufacturer through acquisition and sale by any wholesale  
69 distributor, as defined in § 54.1-3401 and not exempted pursuant to § 54.1-3401.1, until sale to a  
70 pharmacy or other person dispensing or administering the controlled substance. Returns from a pharmacy  
71 to the originating wholesale distributor or pharmaceutical manufacturer shall not be subject to the  
72 pedigree requirements of this section.

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**HOUSE BILL NO. 1966**

Offered January 12, 2011

Prefiled January 11, 2011

A *BILL to amend the Code of Virginia by adding a section numbered 54.1-3316.1, relating to voluntary reporting by pharmacists.*

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Patron—Rust

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Referred to Committee on Health, Welfare and Institutions

**Be it enacted by the General Assembly of Virginia:**

**1. That the Code of Virginia is amended by adding a section numbered 54.1-3316.1 as follows:**

*§ 54.1-3316.1. Voluntary reporting.*

*A. Any person may report to the Board the following information of which he may become aware in his professional capacity:*

*1. That a pharmacist, pharmacy intern, or pharmacy technician is in need of treatment or has been committed or admitted as a patient to a health care facility for treatment of substance abuse or a psychiatric illness that may render such person a danger to himself or others.*

*2. Any evidence that indicates a reasonable probability that a pharmacist, pharmacy intern, or pharmacy technician (i) is or may be professionally incompetent; (ii) has or may have engaged in intentional or negligent conduct that causes or is likely to cause injury to a patient or patients; (iii) is or may be mentally or physically unable to engage safely in the practice of his profession; (iv) has or may have engaged in unethical, fraudulent, or unprofessional conduct as set out in § 54.1-3316 and Board regulations; or (v) has or may have engaged in substance abuse or diversion of prescription drugs. Such evidence shall include, but not be limited to, denial or termination of employment, restrictions imposed on employment, or voluntary resignation to avoid investigation or termination.*

*B. Any person making a report pursuant to this section, providing information pursuant to an investigation, or testifying in a judicial or administrative proceeding as a result of such report shall be immune from any civil liability unless he acted in bad faith or with malicious intent.*

INTRODUCED

HB1966

Joint Commission on Health Care  
900 East Main Street, 1st Floor West  
P. O. Box 1322  
Richmond, VA 23218  
804.786.5445  
804.786.5538 (fax)

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