

Sanctioning **Reference Points** **Instruction Manual**

Board of Pharmacy

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Dear Interested Parties:

In the spring of 2001, the Virginia Department of Health Professions approved a workplan to study sanctioning in disciplinary cases for Virginia's 13 health regulatory boards. The purpose of the study was to "...provide an empirical, systematic analysis of board sanctions for offenses and, based on this analysis, to derive reference points for board members..." The purposes and goals of the study were consistent with state statutes which specify that the Board of Health Professions (BHP) periodically review the investigatory and disciplinary processes to ensure the protection of the public and the fair and equitable treatment of health professionals.

After interviewing Board of Pharmacy's members and staff, a committee of board members, staff, and research consultants assembled a research agenda involving the most exhaustive statistical study of sanctioned Pharmacists ever conducted in the United States. The analysis included collecting over 100 factors on all Board of Pharmacy sanctioned cases in Virginia over a six year period. These factors measured case seriousness, respondent characteristics, and prior disciplinary history. After identifying the factors that were consistently associated with sanctioning, it was decided that the results provided a solid foundation for the creation of sanctioning reference points. Using both the data and collective input from the Board of Pharmacy and staff, analysts developed a usable sanction worksheet as a way to implement the reference system.

In 2010, BHP recommended that the SRPs be evaluated to determine if the program had met the objectives set forth in 2001. The outcomes related to the Board of Pharmacy resulted in several changes to the Sanctioning Reference Points worksheet. This manual is the product of those adopted changes.

Sincerely yours,

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Director
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Cordially,

Elizabeth A. Carter, Ph.D.
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GENERAL INFORMATION

Overview

The Virginia Board of Health Professions has spent the last 10 years studying sanctioning in disciplinary cases. The study has examined all of the Department of Health Professions' (DHP) 13 health regulatory Boards. Focusing on the Board of Pharmacy (BOP), this manual contains background on the project, the goals and purposes of the Sanctioning Reference Points (SRP) system, and a revised offense-based worksheet and grid used to help Board members determine how similarly situated respondents have been treated in the past.

This SRP system is based on a specific sample of cases, and thus only applies to those persons sanctioned by the Virginia Board of Pharmacy. Moreover, the worksheets and grids have not been tested nor validated on any other groups of persons. Therefore, they should not be used to sanction respondents coming before other health regulatory boards, other states, or other disciplinary bodies.

The SRP system is comprised of a single worksheet which scores case type, prior history and offense factors identified using statistical analysis and built upon the Department's effort to maintain standards of practice over time. These factors have been isolated and tested in order to determine their influence on sanctioning outcomes. Sanctioning thresholds found on the offense worksheet recommend a range of sanctions from which the Board may select in a particular case.

In addition to this instruction booklet, separate coversheets and worksheets are available to record the respondent's score, recommended sanction, actual sanction and any reasons for departure (if applicable). The completed coversheets and worksheets will be evaluated as part of an on-going effort to monitor and refine the Sanctioning Reference Points.

These instructions and the use of the SRP system fall within current DHP and BOP policies and procedures. Furthermore, all sanctioning recommendations are those currently available to and used by the Board and are specified within existing Virginia statutes. If an SRP worksheet recommendation is more or less severe than

a Virginia statute or DHP regulation, the existing laws or policy supersedes the worksheet recommendation.

Background

In April of 2001, the Virginia Board of Health Professions (BHP) approved a work plan to conduct an analysis of health regulatory board sanctioning and to consider the appropriateness of developing historically-based sanctioning reference points for health regulatory boards, including the Board of Pharmacy (BOP). In 2010, the Board of Health Professions (BHP) recommended that the SRPs be evaluated to determine if the program had met the objectives set forth in 2001. The purpose of this study was to evaluate the SRP system against its own unique set of objectives. The SRPs were designed to aid board members, staff and the public in a variety of ways. This Effectiveness Study sought to examine whether or not the SRPs were successful, and if not, which areas required improvement.

The Effectiveness Study relied heavily on the completed coversheets and worksheets which record the offense score, respondent score, recommended sanction, actual sanction and any reasons for departure (if applicable). The study resulted in changes to the manual for the BOP. This manual is the result of those adopted changes.

Goals

In 2001, BHP and the BOP cited the following purposes and goals for establishing SRPs:

- Making sanctioning decisions more predictable
- Providing an education tool for new Board members
- Adding an empirical element to a process/system that is inherently subjective
- Providing a resource for BOP members and those involved in proceedings
- "Neutralizing" sanctioning inconsistencies
- Validating Board member or staff recall of past cases
- Reducing the influence of undesirable factors—e.g., Board member ID, overall Board makeup, race or ethnic origin, etc.

- Helping predict future caseloads and need for probation services and terms

Methodology

The fundamental question when developing a sanctioning reference system is deciding whether the supporting analysis should be grounded in historical data (a descriptive approach) or whether it should be developed normatively (a prescriptive approach). A normative approach reflects what policymakers feel sanction recommendations should be, as opposed to what they have been. SRPs can also be developed using historical data analysis with normative adjustments. This approach combines information from past practice with policy adjustments, in order to achieve a more balanced outcome. The SRP manual adopted in 2007 was based on a descriptive approach with a limited number of normative adjustments. The Effectiveness Study was conducted in a similar manner, drawing from historical data to inform worksheet modification.

Qualitative Analysis

Researchers conducted in-depth personal interviews with BOP members staff. Researchers also had informal conversations with representatives from the Attorney General's office and the Executive Director of BHP. The interview results were used to build consensus regarding the purpose and utility of SRPs and to further guide the Effectiveness Study's analysis. Additionally, interviews helped ensure the factors that Board members consider when sanctioning continued to be included during the quantitative phase of the study. Previous scoring factors were examined for their continued relevance and sanctioning influence.

Quantitative Analysis

In 2002, researchers collected detailed information on all BOP disciplinary cases ending in a violation between 1997 and 2002; approximately 361 sanctioning "events" covering close to 450 cases. Over 100 different factors were collected on each case in order to describe the case attributes Board members identified as potentially impacting sanction decisions. Researchers used data available through the DHP case management system

combined with primary data collected from hard copy files. The hard copy files contained investigative reports, Board notices, Board orders, and all other documentation that is made available to Board members when deciding a case sanction.

A comprehensive database was created to analyze the offense and respondent factors which were identified as potentially influencing sanctioning decisions. Using statistical analysis to construct a "historical portrait" of past sanctioning decisions, the significant factors along with their relative weights were derived. These factors and weights were formulated into a sanctioning worksheet with three thresholds, which became the SRPs.

During the Effectiveness Study, researchers used 72 SRP worksheets and coversheets previously completed by Board members. The worksheet factors, scores, sanction recommendations, sanctions handed down, and departure reasons (if any) were coded and keyed over the course of several weeks, creating a database. Additional data on factors board members mentioned as potentially effecting sanctioning was also collected, coded and keyed. That database was then merged with DHP's data system L2K, making more variables eligible for analysis. The resulting database was analyzed to determine any changes in Board sanctioning that may have had an effect on the worksheet recommendations.

Offense and Respondent factors such as patient injury, financial gain, impairment at the time of offense and previous Board orders were analyzed. Researchers re-examined factors previously deemed "extralegal" or inappropriate for the SRP system. For example, type of pharmacy was considered an "extra-legal" factor.

Although, both "legal" and "extra-legal" factors can help explain sanction variation, only those "legal" factors the Board felt should consistently play a role in a sanction decision continued to be included on the worksheets. By using this method, the goal is to achieve more neutrality in sanctioning by making sure the Board considers the same set of "legal" factors in every disciplinary case ending in a violation.

Characteristics of the SRP System

Wide Sanctioning Ranges

The SRPs consider and weigh the circumstances of an offense and the relevant characteristics of the respondent, providing the Board with a sanction range that encompasses roughly 71% of historical practice. This means that 29% of past cases had received sanctions either higher or lower than what the reference points indicate, acknowledging that aggravating and mitigating factors play a role in sanctioning. The wide sanctioning ranges allow the Board to customize on a particular sanction within the broader SRP recommended range.

Three Sets of Sanctioning Factors

The Board indicated early in the SRP study that sanctioning is not only influenced by circumstances directly associated with the case, but also by the respondent's past history. The empirical analysis supported the notion that both offense and respondent factors impacted sanction outcome. To this end, the SRP system, as designed for the Board of Pharmacy, makes use of two sets of factors that combine for a sanctioning outcome that lies within one of three thresholds. The first dimension assesses factors related to case type, the second assesses factors related to the offense and respondent. So a respondent before the Board for an Prescription Error case may also receive points for having had substance abuse problems, or for having a history of disciplinary violations for other types of cases.

Voluntary Nature

The SRP system should be viewed as a decision-aid to be used by the Board of Pharmacy. Sanctioning within the SRP ranges is "totally voluntary," meaning that the system is viewed strictly as a tool and the Board may choose any sanction outside the recommendation. The Board maintains complete discretion in determining the sanction handed down. However, a structured

sanctioning system is of little value if the Board is not provided with the appropriate coversheet and worksheet in every case eligible for scoring. A coversheet and worksheet should be completed in cases resolved by Informal Conference or Pre-Hearing Consent Order. The coversheet and worksheets will be used only after a violation has been determined.

Worksheet Not Used In Certain Cases

The SRPs will not be applied in any of the following circumstances:

- Action by Another Board - When a case which has already been adjudicated by a Board from another state appears before the Virginia Board of Pharmacy, the Board often attempts to mirror the sanction handed down by the other Board. The Virginia Board of Pharmacy usually requires that all conditions set by the other Board are completed or complied with in Virginia. The SRPs do not apply to cases previously heard and adjudicated by another Board.
- Compliance/Reinstatement - The SRPs should be applied to new cases only.
- Confidential Consent Agreements (CCA) - SRPs will not be used in cases settled by CCA.
- Mandatory Suspensions - Virginia law requires that under certain circumstances (conviction of a felony, declaration of legal incompetence or incapacitation, license revocation in another jurisdiction) the license of a physician must be suspended. The sanction is defined by law and is therefore excluded from the Sanctioning Reference Point system.
- Certain case types - When a case type has a sanction that has been pre-defined by the Board of Pharmacy, the SRPs need not be used. Cases of this type include Continuing Education and Inspections.

Using the SRPs

Case Types Covered by the Sanctioning Reference Points

The SRP worksheet is grouped into 3 offense types: Inability to Safely Practice, Professional Practice Issues, and Prescription Error. This organization is based on the most recent historical analysis of Board sanctioning. The SRP factors found on the worksheet are those which proved important in determining sanctioning outcomes.

When multiple cases have been combined for disposition by the Board into one order, only one coversheet and worksheet is completed that encompasses the entire event. If a case (or set of cases) has more than one offense type, one case

type is selected for scoring according to the offense group which appears highest on the following table and receives the highest point value. For example, a pharmacist found in violation of both a labeling error and personal use would receive seventy points, since Inability to Safely Practice is above Prescription Error on the list and receives the most points. If an offense type is not listed, find the most analogous offense type and use the appropriate score. The case type that has been selected from the list below is the only case type that receives points on the sanctioning worksheet. This table is used for Pharmacists only.

Sanctioning Reference Points Case Type Table

Inability to Safely Practice	<p>Impairment due to use of alcohol, illegal substances, or prescription drugs or incapacitation due to mental, physical or medical conditions</p> <p>Dispensing in violation of DCA (to include dispensing for non medicinal purposes, not in accordance with dosage, filling an invalid prescription, or dispensing without a relationship), prescription forgery, drug adulteration, patient deprivation, stealing drugs from patients, or personal use</p>	70
Professional Practice Issues	<p>Falsification/alteration of patient records</p> <p>Business Practice Issues</p> <p>Advertising, default on guaranteed student loan, solicitation, records, audits, required report not filed or disclosure</p> <p>Failure to maintain security of controlled substances</p> <p>Disclosing unauthorized client information without permission or necessity</p>	25
Prescription Error	<p>Labeling, dispensing, and administration errors</p> <p>Failure to provide counseling</p> <p>Standard of Care - Other: cases involving patient care that cannot fit adequately into any other case type</p>	10

Completing the Coversheet

The coversheet (shown on page 9) are completed to ensure a uniform record of each case and to facilitate recordation of other pertinent information critical for continued system monitoring, evaluation and improvement. If the Board feels the sanctioning grid does not recommend an appropriate sanction, the Board should depart either high or low when handing down a sanction.

If the Board disagrees with the sanction recommendation and imposes a sanction greater or less than the recommended sanction, “Yes” should be checked and a short explanation should be recorded on the coversheet. The explanation should identify the factors and reasons for departure (see examples below). This process ensures worksheets are revised to reflect current Board practice and to maintain the dynamic nature of the system. For example, if a particular reason is continually cited, the Board can examine the issue more closely to determine if the worksheets should be modified to better reflect Board practice.

Aggravating and mitigating circumstances that may influence Board decisions can include, but should not be limited to, such things as:

- Severity of the incident
- Age of prior record
- Dishonesty/Obstruction
- Motivation
- Remorse
- Cause for the action
- Restitution/Self-corrective action
- Multiple offenses/Isolated incident

A space is provided on the coversheet to record the reason(s) for departure. Due to the uniqueness of each case, the reason(s) for departure may be varied. Sample scenarios are provided below:

Departure Example #1

Sanction Grid Result: Monetary Penalty

Imposed Sanction: No Sanction

Reason(s) for Departure: Respondent was particularly remorseful and had proof of corrective action

Departure Example #2

Sanction Grid Result: Monetary Penalty

Imposed Sanction: Probation with Terms

Reason(s) for Departure: Respondent lacked insight into cause of violation. Further monitoring was deemed necessary.

The Sanction Reference Point coversheet and worksheet, once completed, are confidential under the Code of Virginia. However, complete copies of the Sanction Reference Point Manual, including blank coversheets and worksheets, can be found on the Department of Health Professions web site: www.dhp.state.va.us (paper copy also available on request).

Completing the Worksheet

Instructions for case scoring are contained adjacent to each worksheet in subsequent sections of this manual. Instructions are provided for each line item of each worksheet and should be referenced to ensure accurate scoring for a specific factor. When scoring a worksheet, the scoring weights assigned to a factor on the worksheet cannot be adjusted. The scoring weights can only be applied as ‘yes or no’ with all or none of the points applied. In instances where a scoring factor is difficult to interpret, the Board has final say in how a case is scored.

Determining a Specific Sanction

The Sanction thresholds have three separate sanctioning outcomes: No Sanction/Reprimand/CE, Monetary Penalty, and Treatment/Monitoring/Recommend Formal. The table below lists the most frequently cited sanctions under the three sanctioning outcomes. After considering the sanction recommendation, the Board should fashion a more detailed sanction(s) based on the individual case circumstances.

Sanctioning Reference Points Threshold Table

Worksheet Threshold	Available Sanction	Fine Amounts
No Sanction/Reprimand/CE	No Sanction Reprimand Continuing Education	N/A
Monetary Penalty	Monetary Penalty	\$250 to \$1500
Treatment/Monitoring/ Recommend Formal	Probation Stayed Suspension Revocation Suspension Revoke Right to Renew Suspend Right to Renew Recommend Formal Terms: Begin/ continue AA, NA, Caduceus, HPMP Random drug screenings Drug, alcohol, mental or physical evaluation Quarterly self reports Quarterly performance evaluation from employer Written notification to PIC Inform Board of any changes in employment Notarized affidavit attesting to read/follow Ch.25.2 of Code of VA Take/pass VA Drug Law Exam Shall not be Pharmacist in Charge Inform Board upon resuming practice Inspection Written evidence to Board of proper recordation of ingredients of compounded drugs Report any medication errors to Board within 10 days of occurrence Other practice restriction	\$1000 and up

Sanctioning Reference Points Coversheet for Pharmacists

Case
Number(s):

--	--	--	--	--	--	--

--	--	--	--	--	--	--

--	--	--	--	--	--	--

Respondent
Name:

License
Number:

Sanction 0-35

Threshold 36-115

Level: 116 and up

Imposed No Sanction

Sanction(s): Reprimand

Continuing Education

Monetary Penalty

Probation: _____ duration in months

Stayed Suspension: _____ duration in months

Revocation

Suspension

Revoke Right to Renew

Suspend Right to Renew

Recommend Formal

Other Sanction: _____

Terms: _____

Was imposed sanction a departure from the recommendation? No Yes, give reason below

Reasons for Departure from Sanction Grid Result: _____

Worksheet Preparer's Name:

Date Worksheet Completed:

Case Type

Step 1: (score only one)

Enter the point value that corresponds to the case type. If a case has multiple aspects, enter the point value for the one most serious case type that is highest on the list.

- A. Enter “70” if case involves an Inability to Safely Practice. These cases include:
- Inability to Safely Practice: Impairment due to use of alcohol, illegal substances, or prescription drugs or incapacitation due to mental, physical or medical conditions
 - Drug Related – Patient Care: Dispensing in violation of DCA (to include dispensing for non-medicinal purposes, excessive prescribing, not in accordance with dosage, filling an invalid prescription, or dispensing without a relationship), prescription forgery, drug adulteration, patient deprivation, stealing drugs from patients, or personal use
- B. Enter “25” if the case involves Professional Practice Issues. These cases include:
- Business Practice Issues: records, audits, required report not filed, or disclosure
 - Drug Related – Security: Failure to maintain security of controlled substances
 - Fraud – Patient Care: falsification/alteration of patient records
 - Confidentiality Breach: disclosing unauthorized client information without permission or necessity
- C. Enter “10” if the case involves a Prescription Error. These cases include:
- Standard of Care – Medication/Prescription: labeling, dispensing, and administration errors, failure to provide counseling as well as other medication/prescription related issues
 - Standard of Care – Other

Offense and Respondent

Step 2: (score all that apply)

- A. Enter “60” if there was financial or other material gain from the offense.
- B. Enter “50” if the respondent was impaired at the time of the incident. Impairment can include drugs, alcohol, mental and/or physical.
- C. Enter “50” if the respondent has had any past difficulties or treatment in any of the following areas: drugs, alcohol, mental health and/ or physical health. Difficulties in these areas must be relevant to the current case and treatment must have been provided by a bono fide health care practitioner.
- D. Enter "35" if there are two or more concurrent founded violations during the same proceeding. This includes two or more cases against a respondent heard at the same time, with violations for each case.
- E. Enter “35” if there was an act of commission. An act of “commission” is interpreted as purposeful, intentional, or clearly not accidental.
- F. Enter “15” if the patient was injured. Patient injury includes any injury reported by the consumer regardless of follow up treatment.
- G. Enter “5” if the respondent has had one or more prior Board violations.

Step 3: Combine all for Total Worksheet Score. Locate the Total Worksheet Score with the Sanction Threshold Levels table at the bottom of the worksheet. The scores correspond to one of the three SRP recommendations.

The use of the Sanction Reference Points is voluntary. In addition, the worksheet sanction result may be combined with sanctions from lower sanction thresholds. For example, should a respondent fall within the “Monetary Penalty” area with a score of 40, the Board may choose a sanction package that includes a “Monetary Penalty” and a “Reprimand” and still be in agreement with the SRP recommendation.

Case Type (score only one)	<u>Points</u>	<u>Score</u>
A. Inability to Safely Practice	70	_____
B. Professional Practice Issues	25	_____
C. Prescription Error	10	_____

Offense and Respondent (score all that apply)		
A. Financial/Material gain	60	_____
B. Respondent impaired during incident	50	_____
C. Any past substance abuse or treatment	50	_____
D. Multiple violations associated with case	35	_____
E. Act of commission	35	_____
F. Patient injury	15	_____
G. Any prior violations	5	_____

Total Worksheet Score

Score	Sanctioning Recommendations	Fine Amounts
0-35	No Sanction/Reprimand/CE	N/A
36-115	Monetary Penalty	\$250 to \$1500
116 and up	Treatment/Monitoring/Recommend Formal	\$1000 and up

Respondent Name: _____

Date: _____