

SANCTIONING REFERENCE POINTS

INSTRUCTION MANUAL

Board of Pharmacy

Virginia Department
of Health Professions

Board of Pharmacy
Guidance Document 110-21
Adopted September 12, 2007



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COMMONWEALTH OF VIRGINIA

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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 this study are consistent with state statutes which specify that the Board of Health Professions periodically review the investigatory and disciplinary processes to ensure the protection of the public and the fair and equitable treatment of health professionals.

Each health regulatory board hears different types of cases, and as a result, considers different factors when determining an appropriate sanction. After interviewing Board of Pharmacy members and staff, a committee of Board members, staff, and research consultants assembled a research agenda involving one of the most exhaustive statistical studies of sanctioned Pharmacists in the United States. The analysis included collecting over 100 factors on all Board of Pharmacy sanctioned cases in Virginia over a 6-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 sanction reference points. Using both the data and collective input from the Board of Pharmacy and staff, analysts then developed a usable sanctioning worksheet as a way to implement the reference system.

By design, future sanction recommendations will encompass, on average, about 79% of past historical sanctioning decisions; an estimated 21% of future sanctions will fall above or below the sanction point recommendations. This allows considerable flexibility when sanctioning cases that are particularly egregious or less serious in nature. Consequently, one of the most important features of this system is its voluntary nature; that is, the Board is encouraged to depart from the reference point recommendation when aggravating or mitigating circumstances exist.

Equally important to recommending a sanction, the system allows each respondent to be evaluated against a common set of factors—making sanctioning more predictable, providing an educational tool for new Board members, and neutralizing the possible influence of "inappropriate" factors (e.g., race, sex, attorney presence, identity of Board members). As a result, the following reference instrument should greatly benefit Board members, health professionals and the general public.

Sincerely yours,

Handwritten signature of Sandra Whitley Ryals in black ink.

Sandra Whitley Ryals
Director

Cordially,

Handwritten signature of Elizabeth A. Carter in black ink.

Elizabeth A. Carter, Ph.D.
Executive Director
Virginia Board of Health Professions

Table of Contents

General Instructions

Overview	5
Background	6
Goals	6
Methodology	6
Qualitative Analysis.....	6
Quantitative Analysis	7
Wide Sanctioning Ranges	7
Three Sets of Sanctioning Factors	8
Voluntary Nature	8
Worksheets Not Used in Certain Cases	9
Case Selection When Multiple Cases Exist	10
Sanctioning Reference Points Case Type Table	10
Completing the Coversheet and Worksheet	11
Sanctioning Worksheet	11
Coversheet	11
Determining a Specific Sanction	12
Sanctioning Reference Points Threshold Table.....	12
Sanctioning Reference Points Coversheet	13
Sanctioning Reference Points Worksheet Instructions.....	14
Sanctioning Reference Points Worksheet	15

Overview

The Virginia Board of Health Professions has spent the last 4 years studying sanctioning in disciplinary cases. The study is examining all 13 health regulatory boards, with the greatest focus most recently on the Board of Pharmacy. The Board of Pharmacy is now in a position to implement the results of the research by using a set of voluntary *Sanctioning Reference Points*. This manual contains some background on the project, the goals and purposes of the system, and the offense-based sanction worksheet that will be used to help Board members determine how a similarly situated respondent has been treated in the past. This sanctioning 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 worksheet has not been tested or validated on any other groups of persons. Therefore, they should not be used at this point to sanction respondents coming before other health regulatory boards, other states, or other disciplinary bodies.

The Sanctioning Reference system is comprised of a single worksheet which scores case type, prior history and offense factors identified using statistical analysis. 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 Sanctioning Reference Points system fall within current Department of Health Professions and Board of Pharmacy policies and procedures. Furthermore, all sanctioning recommendations are those currently available to and used by the Board and are specified within existing Virginia statutes.

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). The Board of Health Professions and project staff recognize the complexity and difficulty in sanction decision-making and have indicated that for any sanction reference system to be successful, it must be *“developed with complete Board oversight, be value-neutral, be grounded in sound data analysis, and be totally voluntary”*—that is, the system is viewed strictly as a Board decision tool.

Goals The Board of Health Professions and the Board of Pharmacy cite the following purposes and goals for establishing Sanctioning Reference Points:

- Making sanctioning decisions more predictable
- Providing an education tool for new Board members
- Adding an empirical element to a system that is inherently subjective
- Providing a resource for BOP and those involved in proceedings.
- “Neutralizing” sanctioning inconsistencies
- Validating Board member or staff recall of past cases
- Constraining 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*. Sanctioning reference points can also be developed using historical data analysis with normative adjustments to follow. This approach combines information from past practice with policy adjustments, in order to achieve some desired outcome. The Board of Pharmacy chose a descriptive approach with a limited number of normative adjustments.

■ Qualitative Analysis

Researchers conducted in-depth personal interviews of some past and all current BOP members, Board staff, and representatives from the Attorney General’s office. The interview results were used to build consensus regarding the purpose and utility of sanctioning reference points and to further frame the analysis. Additionally, interviews helped ensure the factors that Board members consider when sanctioning were included during the quantitative phase of the study. A literature review of sanctioning practice across the United States was also conducted.

Methodology, continued**■ Quantitative Analysis**

Researchers analyzed detailed information on 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 are the basis of the Sanctioning Reference Points.

Offense factors such as patient injury, financial gain and case severity (priority level) were analyzed as well as prior history factors such as substance abuse, and previous Board orders. Some factors were deemed inappropriate for use in a structured sanctioning reference system. For example, respondent gender and presence of an attorney are considered “extra-legal” factors, and were explicitly excluded from the sanction reference points. Although many factors, both “legal” and “extra-legal” can help explain sanction variation, only those “legal” factors the Board felt should consistently play a role in a sanction decision were included in the final product. By using this method, the hope is to achieve more neutrality in sanctioning, by making sure the Board considers the same set of “legal” factors in every case.

Wide Sanctioning Ranges

The Sanctioning Reference Points 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 79% of historical practice. This means that 21% 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 recognize that the Board will sometimes reasonably disagree on a particular sanction outcome, but that a broad selection of sanctions fall within the recommended range.

Any sanction recommendation the Board derives from the Sanctioning Reference Points worksheets must fall within Virginia law and regulations. If a Sanctioning Reference Point worksheet recommendation is more or less severe than a Virginia statute or DHP regulation, the existing laws or policies supercede any worksheet recommendation.

Three Sets of Sanctioning Factors

The Board indicated early in the study that sanctioning is influenced by variety of circumstances beyond the instant offense. The empirical analysis supported the notion that not only case type but offense factors and prior history impacted sanction outcomes. To this end, the Sanction Reference Points system, as designed for the Board of Pharmacy, makes use of three 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 the third dimension relates to prior history.

So a respondent before the Board for an records/inspections/audits case may also receive points for having had substance abuse problems, or for having a history of disciplinary violations for other types of cases. In the first dimension points are assigned for the type of case the Board is currently considering. The second dimension assigns points for factors related to the offense. For example, the respondent may receive points if they were impaired at the time of the offense. The last dimension assigns points for prior history. In this category, a respondent's prior Board orders and/or any past substance abuse are considered.

Voluntary Nature

The Sanctioning Reference Points system is a tool to be utilized by the Board of Pharmacy. Compliance with the Sanctioning Reference Points is voluntary. The Board will use the system as a reference tool and may choose to 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 Conferences and Consent Orders that come before Informal Conference committees. The coversheet and worksheets will be referenced by Board members during Closed Session.

**Worksheets Not Used
in Certain Cases**

The Sanctioning Reference Points will not be applied in any of the following circumstances:

- Formal Hearings — Sanction Reference Points will not be used in cases that reach a Formal Hearing level.
- 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 pharmacist must be suspended. The sanction is defined by law and is therefore excluded from the Sanctioning Reference Point system.
- Compliance/reinstatements – The Sanctioning Reference Points should be applied to new cases only.
- 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 Sanctioning Reference Points do not apply as the case has already been heard and adjudicated by another Board.
- Confidential Consent Agreements (CCA) - Sanction Reference Points will not be used in cases settled by CCA.

Case Selection When Multiple Cases Exist

When multiple cases have been combined into one “event” (one order) for disposition by the Board, only one coversheet and worksheet should be completed and it should encompass 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 wrong drug error and personal drug use would receive fifty 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.

Sanctioning Reference Points Case Type Table

Case Type	Included Categories	Points Assignment
Inability to Safely Practice	Incapacitation – mental/physical Impairment – drugs/alcohol Inability to Safely Practice - other Drug Related - Excessive Dispensing Drug Related – Security Drug Related - Obtaining Drugs by Fraud Drug Related – Personal Use Drug Related – Other	50
Professional Practice Issues	Criminal Activity Business Practice Issues Fraud Unlicensed Activity Records/Inspections/Audits Unprofessional Conduct	35
Prescription Error	Strength/Quantity Error Directions/Expired Medications Error Wrong Drug Error Wrong Patient/Physician Name Error Generic/Brand Error	10

Completing the Coversheet and Worksheet

Ultimately, it is the responsibility of the BOP to complete the Sanction Reference Point coversheet and worksheet in all applicable cases.

The information relied upon to complete a coversheet and worksheet is derived from the case packet provided to the Board and respondent. It is also possible that information discovered at the time of the informal conference may impact worksheet scoring. 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).

Sanctioning 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.

Coversheet

The coversheet is completed to ensure a uniform record of each case and to facilitate recodation of other pertinent information critical for system monitoring and evaluation.

If the Board feels the sanctioning threshold does not recommend an appropriate sanction, the Board is encouraged to 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, a short explanation can be recorded on the coversheet. The explanation could identify the factors and the reasons for departure. This process will ensure worksheets are revised appropriately to reflect current Board practice. 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:

- Prior record
- Dishonesty/Obstruction
- Motivation
- Remorse
- Victim vulnerability
- 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 wide-ranging. Sample scenarios are provided on the following page.

Coversheet, continued**Departure Example #1**

Sanction Grid Result: Remove from practice.

Imposed Sanction: Probation with terms – practice restriction.

Reason(s) for Departure: Respondent was particularly remorseful and had already begun corrective action.

Departure Example #2

Sanction Grid Result: Reprimand.

Imposed Sanction: Probation – practice monitoring.

Reason(s) for Departure: Respondent may be trending towards future violations, implement oversight now to avoid future problems.

Determining a Specific Sanction

The Sanction thresholds have three separate sanctioning outcomes: Monitoring/Treatment/Refer to Formal, Reprimand/Monetary Penalty, and Knowledge Based. The table below lists the most frequently cited sanctions under the three sanctioning outcomes that are part of the sanction threshold. 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 Sanctions
Monitoring/ Treatment/ Refer to Formal	Recommend Formal (revocation or suspension may result) Suspension Stayed Suspension Probation Terms Quarterly performance evaluations from employer Written notification to pharmacist in charge Quarterly self reports/DEA forms Inform board of any changes in employment Random drug screenings Begin/continue AA/NA, caduceus, etc. Inform board upon resuming practice Continue in therapy and therapist provides quarterly reports Aftercare/peer assistance group contract – continue Chemical dependency/psych/mental/phys/ evaluation Quarterly reports from probation/parole officer Provide board with court order
Reprimand/ Monetary Penalty	Monetary Penalty Reprimand Terms Shall not be Pharmacist in Charge Abstain from alcohol and controlled substances
Knowledge Based	No Sanction Terms Continuing Education – general Drug Diversion Awareness Program

Sanctioning Reference Points - Coversheet for Board of Pharmacy

- Complete *Case Type Score* section on the Sanctioning Reference Point Worksheet.
- Complete the *Offense Factor* section on the Sanctioning Reference Point Worksheet.
- Complete the *Prior History* section on the Sanctioning Reference Point Worksheet.
- Determine the *Recommended Sanction* using the scoring results and the *Sanction Thresholds*.
- Complete this Coversheet.

Case Number(s)

Respondent Name _____
Last First Title

License Number _____

Case type Inability to Safely Practice
 Professional Practice Issues
 Prescription Error

Sanction Threshold Result Knowledge Based
 Reprimand/Monetary
 Monitoring/Treatment/Refer to Formal

Imposed Sanction Revocation
 Suspension
 Stayed Revocation - Immediate
 Stayed Suspension - Immediate
 Probation - duration in months _____
 Monetary Penalty - enter amount \$ _____
 Reprimand
 No Sanction
 Terms: _____

Reasons for Departure from Sanction Threshold Result _____

Worksheet Prepared by: _____ Date completed: _____

Confidential pursuant to §54.1-2400.2 of the Code of Virginia.

Board of Pharmacy - Sanctioning Reference Points WORKSHEET INSTRUCTIONS

Case Type

(score only one, see list on page 5)

- A. Enter "50" if case involves an Inability to Safely Practice. These cases include:
- Incapacitation—mental/physical
 - Impairment—drugs/alcohol
 - Inability to Safely Practice—other
 - Drug Related—excessive dispensing
 - Drug Related—security
 - Drug Related—obtaining drugs by fraud
 - Drug Related – personal use
 - Drug Related – other
- B. Enter "35" if the case involves Professional Practice Issues. These cases include:
- Criminal Activity
 - Business Practice Issues
 - Fraud
 - Unlicensed Activity
 - Records/Inspections/Audits
 - Unprofessional Conduct
- C. Enter "10" if the case involves a Prescription Error. These cases include:
- Strength/Quantity
 - Directions/Expired Medications
 - Wrong Drug
 - Wrong Patient/Physician Name
 - Generic/Brand

Offense Factors Scoring

(score all that apply)

- B. Enter "70" in cases where an individual may have committed an act or is highly likely to commit an act that constitutes significant and substantial danger to the health and safety of any person (Priority A) or in cases where an individual may have committed a harmful act to another person but does not pose an imminent threat to public safety (Priority B).

- B. Enter "50" if there was financial or other material gain from the offense.
- C. Enter "50" if there was an act of commission. An act of "commission" is interpreted as purposeful, intentional, or clearly not accidental.
- D. Enter "50" if the respondent was impaired at the time of the incident. Impairment can include drugs, alcohol, mental and/or physical.
- E. Enter "10" if the patient was injured. Patient injury includes any injury reported by the consumer regardless of follow up treatment.

Prior History Scoring

(score all that apply)

- A. Enter "30" 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 bona fide health care practitioner.
- B. Enter "10" if the respondent has had one or more prior Board violations.
- C. Enter "10" if the respondent has had a prior violation similar to the current case. Cases are considered similar when they fall within the same category.

Inability to Safely Practice:

- Incapacitation – mental/physical
- Impairment – drugs/alcohol
- Inability to Safely Practice - other
- Drug Related - excessive dispensing
- Drug Related – security

- Drug Related - obtaining drugs by fraud
- Drug Related – personal use
- Drug Related – other

Professional Practice Issues

- Criminal Activity
- Business Practice Issues
- Fraud
- Unlicensed Activity
- Records/Inspections/Audits
- Unprofessional Conduct

Prescription Error

- Strength/Quantity
- Directions/Expired Medications
- Wrong Drug
- Wrong Patient/Physician Name
- Generic/Brand

Total Score

Sum all points on the worksheet and locate the sanction recommendation on the threshold table provided.

Scoring Outcome

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 "Reprimand/Monetary" area with a score of 40, the Board may choose a sanction package that includes a "Monetary Penalty" and a "Knowledge Based" sanction.

Board of Pharmacy - Sanctioning Reference Points WORKSHEET

Case Type (score only one)	Points	Score	
Inability to safely practice	50	_____	score only one
Professional Practice Issues	35	_____	
Prescription Error	10	_____	

Offense Factors (score all that apply)			
Priority A or B	70	_____	score all that apply
Financial/Material gain	50	_____	
Act of commission	50	_____	
Respondent impaired during incident	50	_____	
Patient injured	10	_____	

Prior History (score all that apply)			
Any past substance abuse or treatment	30	_____	score all that apply
One or more prior Board violations	10	_____	
Any prior similar Board violations	10	_____	

Total Respondent Score

THRESHOLDS		
Knowledge Based		0-30
Reprimand/Monetary		31-120
Monitoring/Treatment/Refer to Formal		121 or more

Respondent Name: _____ Date: _____