MARYLAND REGISTER

Proposed Action on Regulations

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee	TO BE COMPLETED BY DSD
	07/01/2016	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 8/5/2016

2. COMAR Codification

Title	Subtitle	Chapter	Regulation
10	32	22	01-.09

3. Name of Promulgating Authority

Department of Health and Mental Hygiene

4. Name of Regulations Coordinator Michele Phinney

Telephone Number 410-767-5623

Mailing Address

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5. Name of Person to Call About this Document Sandi Van Horn

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Email Address
sandi.vanhorn@maryland.gov

6. Check applicable items:

X- New Regulations

_ Amendments to Existing Regulations

Date when existing text was downloaded from COMAR online: .

_ Repeal of Existing Regulations

_ Recodification

_ Incorporation by Reference of Documents Requiring DSD Approval

_ Reproposal of Substantively Different Text:

: Md. R

(vol.) (issue) (page nos) (date)

Under Maryland Register docket no.: --P.

7. Is there emergency text which is identical to this proposal:

_ Yes **X-** No

8. Incorporation by Reference

_ Check if applicable: Incorporation by Reference (IBR) approval form(s) attached and 18 copies of documents proposed for incorporation submitted to DSD. (Submit 18 paper copies of IBR document to DSD and one copy to AELR.)

9. Public Body - Open Meeting

X- OPTIONAL - If promulgating authority is a public body, check to include a sentence in the Notice of Proposed Action that proposed action was considered at an open meeting held pursuant to General Provisions Article, §3-302(c), Annotated Code of Maryland.

_ OPTIONAL - If promulgating authority is a public body, check to include a paragraph that final action will be considered at an open meeting.

10. Children's Environmental Health and Protection

_ Check if the system should send a copy of the proposal to the Children's Environmental Health and Protection Advisory Council.

11. Certificate of Authorized Officer

I certify that the attached document is in compliance with the Administrative Procedure Act. I also certify that the attached text has been approved for legality by Noreen M. Rubin, Assistant Attorney General, (telephone #410-767-6917) on April 20, 2016. A written copy of the approval is on file at this agency.

Name of Authorized Officer

Van T. Mitchell

Title	**Telephone No.**
Secretary	410-767-6500

Date

June 30, 2016

Title 10
DEPARTMENT OF HEALTH AND MENTAL HYGIENE
Subtitle 32 BOARD OF PHYSICIANS
10.32.22 Mandated Reporting to the Board

Authority: Health Occupations Article, §§14-413, 14-414, 14-5A-18, 14-5B-15, 14-5C-18, 14-5E-18, 14-5F-18, and 15-103, Annotated Code of Maryland

Notice of Proposed Action

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The Secretary of Health and Mental Hygiene proposes to adopt new Regulations .01—.09 under a new chapter COMAR 10.32.22 Mandated Reporting to the Board.
This action was considered at a public meeting on November 18, 2015, notice of which was given by publication on the Board's Website at http://www.mbp.state.md.us/forms/nov15Bagenda.pdf from October 30, 2015 through November 18, 2015 pursuant to General Provisions Article, §3-302(c), Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to define and clarify precisely for hospitals and other reporting entities what changes in employment or privileges require reporting to the Board of Physicians (the "Board"). Based on the 2013 amendments to the Medical Practice Act, Health Occupations Article, §§14-413 and 14-414, Annotated Code of Maryland, and a recommendation by the Department of Legislative Services ("DLS") in its 2011 Sunset Report, the Board conducted extensive outreach and received helpful input from all interested parties and stakeholders before developing these proposed regulations. Because of the reporting entities' apparent confusion about the instances that require reporting, the proposed regulations provide explicit, practical, and easily understandable guidance on what they are required to report, and so avoid the imposition of civil penalties for failure to do so.

Historically, since the 1977 enactment of the reporting statute, compliance with its provisions has been extremely low. The DLS, in its 2011 Sunset Report, found that underreporting by hospitals remains a significant problem. Hospitals have repeatedly failed to report terminations, suspensions, involuntary resignations and other actions adversely affecting physician privileges and patient care. As a result, the DLS strongly recommended that the Board exercise its authority to assess a civil penalty for non-compliance. Once the requirements have been clarified in these regulations, the Board anticipates few violations and little or no economic impact, but believes it is necessary for the Board to exercise its statutory authority to impose a civil penalty if there is a violation.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499; TTY:800-735-2258, or email to dhmh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through September 6, 2016. A public hearing has not been scheduled.

Economic Impact Statement Part C

A. Fiscal Year in which regulations will become effective: FY 2017
B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?

C. If 'yes', state whether general, special (exact name), or federal funds will be used:

D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:

E. If these regulations have no economic impact under Part A, indicate reason briefly: These proposed regulations will have an economic impact only on those reporting entities that violate the law by failing to report certain changes to the Board. The Board anticipates that with this new guidance on when reporting is required, reporting entities will comply with the law and the Board will have to impose few, if any, civil penalties for failing to report.
F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.
See E. above.
G. Small Business Worksheet:

Attached Document:

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 32 BOARD OF PHYSICIANS

10.32.22 Mandated Reporting to the Board

Authority: *Health Occupations Article, §§14-413, 14-414, 14-5A-18, 14-5B-15, 14-5C-18, 14-5E-18, 14-5F-18, and 15-103, Annotated Code of Maryland*

.01 Scope.

This chapter governs reporting requirements to the Board of Physicians concerning health care providers and naturopathic doctors by:

A. Hospitals;
B. Related institutions;
C. Employers of allied health providers or naturopathic doctors;
D. Health care facilities;
E. State agencies;
F. Health care providers;
G. Naturopathic doctors; and
H. Alternative health systems.

.02 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Abandon" means a health care provider's withdrawal from the care and treatment of a patient during the course of treatment without giving reasonable notice to the patient or providing a competent replacement.

(2) "Academic probation" means a program of heightened monitoring of an individual in a postgraduate training program imposed because of academic or performance deficiencies.

(3) "Acts" means Health Occupations Article, Title 14, including subtitles 5A, 5B, 5C, 5E, and 5F, and Title 15, Annotated Code of Maryland.

(4) "Administrative suspension" means an action imposed by a reporting entity restricting a health care provider's privileges or hours or scope of employment for failure of the health care provider to comply with the bylaws, rules, policies, or procedures of the reporting entity.

(5) "Allied health provider" means an individual who is licensed by the Board under Health Occupations Article, Title 14, subtitles 5A, 5B, 5C, and 5E, and Title 15, Annotated Code of Maryland.

(6) "Alternative health system" has the same meaning as alternative health care system as defined in Health Occupations Article, §1-401(a), Annotated Code of Maryland.

(7) "Board" means the State Board of Physicians.

(8) "Change" means any of the following actions by a reporting entity:

(a) Terminating or failing to renew a health care provider's staff privileges or employment or contract with the reporting entity, or terminating or refusing or failing to renew or to extend the term of the academic contract of an individual in a postgraduate training program;

(b) Taking disciplinary action against a health care provider who continues to be employed, enjoy privileges, or contract with the reporting entity, including but not limited to:

(i) Suspension;
(ii) Placement on probation; or
(iii) Restriction or limitation of privileges or duties;

(c) Accepting an involuntary resignation as defined in this regulation;

(d) Accepting or acquiescing to an involuntary leave of absence as defined in this regulation;

(e) Accepting or acquiescing to an involuntary alteration in practice as defined in this regulation;

(f) Requesting that a health care staffing entity cease furnishing the services of a particular health care provider;

(g) In the case of a physician, denying:

(i) By a hospital or related institution, an application for staff privileges;

(ii) By an alternative health care system, an application for employment; or

(h) Terminating the delegation agreement of a physician assistant.

(9) "Failure to report" means the failure of a reporting entity to file a report with the Board as mandated by this chapter.

(10) "Focused professional practice evaluation (FPPE)" means any process used by a reporting entity to assess the competence or proficiency of a health care provider in a certain clinical skill, activity, or procedure.

(11) "Focused review" has the same meaning as "focused professional practice evaluation" as defined in this regulation.

(12) "Good standing" means the health care provider is not suspended, on probation, or subject to any pending disciplinary proceedings, an involuntary alteration in practice, or an involuntary leave of absence, as these terms are defined in this regulation.

(13) "Health care facility" has the meaning stated in Health-General Article, §19-114, Annotated Code of Maryland.

(14) "Health care provider" means a physician, an allied health provider, or an individual in a postgraduate training program.

(15) "Health care staffing entity" means a business entity that contracts to provide, directly or indirectly, the personal health care services of one or more health care providers to a reporting entity.

(16) Hospital.

(a) "Hospital" has the meaning stated in Health-General Article, §19-301, Annotated Code of Maryland.

(b) "Hospital" includes, with respect to an institution that meets the requirements of Health-General Article, §19-301, Annotated Code of Maryland, any entity which:

(i) Operates or administers a postgraduate training program; or

(ii) Has the authority to hire or discipline or to grant, deny, limit, or modify the contract or privileges of an individual in a postgraduate training program.

(17) "Individual in a postgraduate training program" means an intern, an assistant resident, a resident, or a clinical fellow in a postgraduate training program as defined in this regulation.

(18) "Involuntary alteration in practice" means a modification in the privileges, employment, or contractual duties of a health care provider, whether self-initiated by the health care provider, mutually agreed upon, or requested or suggested by the reporting entity:

(a) After the health care provider has been notified of pending discharge or termination of privileges or a contract, or pending proceedings possibly leading to discharge or termination of privileges or a contract;

(b) While the health care provider is under investigation or subject to an inquiry, a practice review, a focused review, or an FPPE;

(c) After the health care provider has been notified that an investigation or inquiry may begin; or

(d) After the health care provider has been asked to respond to a complaint made to the reporting entity.

(19) "Involuntary leave of absence" means a hiatus, however designated, during which a health care provider does not exercise staff privileges or fulfill the duties of employment or a contract, whether the hiatus was self-initiated, mutually agreed upon, or requested or imposed by the reporting entity, where the health care provider commenced the hiatus:

(a) After being notified of pending discharge or termination of privileges or a contract, or pending proceedings possibly leading to discharge or termination of privileges or a contract;

(b) While under investigation or subject to an inquiry, a practice review, a focused review, or an FPPE;

(c) After being notified that an investigation or inquiry may begin; or

(d) After being asked to respond to a complaint made to the reporting entity.

(20) "Involuntary resignation" means a health care provider's relinquishment of privileges, employment, or a contract with a reporting entity, whether the relinquishment was self-initiated, mutually agreed upon, or had been requested by the reporting entity, and however designated by the health care provider or the reporting entity, if the health care provider resigned:

(a) After being notified that discharge or termination of privileges, employment, or a contract, or that proceedings possibly leading to discharge or termination of privileges, employment, or a contract, would occur if the health care provider would not resign;

(b) While under investigation or subject to an inquiry, a practice review, a focused review, or an FPPE;

(c) After being notified that an investigation or inquiry may begin; or

(d) After being asked to respond to a complaint made to the reporting entity.

(21) "Licensed physician" means an individual, including doctor of osteopathy, who is licensed by the Board to practice medicine.

(22) "Mandated report" means any report required under the Acts or this chapter.

(23) "Naturopathic doctor" means an individual who is licensed by the Board under Health Occupations Article, Title14, Subtitle 5F, Annotated Code of Maryland.

(24) “Privileges” means authorization granted by a reporting entity to a health care provider to provide specific care, treatment, diagnostic services, or other services to patients.

(25) “Postgraduate training program” means a program of academic training that meets the requirements of COMAR 10.32.01 and 10.32.07.

(26) “Related institution” has the meaning stated in Health-General Article, §19-301, Annotated Code of Maryland.

(27) “Reporting entity” means:

(a) A hospital, a related institution, or an alternative health system, as these terms are defined in this regulation; and

(b) An employer of an allied health provider that is not a hospital, a related institution, or an alternative health system.

(28) “Voluntary alteration in practice” means a modification in the privileges, employment, or contractual duties made with respect to a health care provider in good standing that is not an involuntary alteration in practice as defined in this regulation.

(29) “Voluntary leave of absence” means a hiatus from providing health care services taken by a health care provider in good standing that is not an involuntary leave of absence as defined in this regulation.

(30) “Voluntary resignation” means the relinquishment of privileges, employment, or a contract with a reporting entity taken by a health care provider in good standing that is not an involuntary resignation as defined in this regulation.

.03 Mandated Reports.

A. Subject to the limitations set out in §§B and C of this regulation, the reporting entity shall report to the Board in writing any change made with respect to a health care provider:

(1) Whom the reporting entity employs;

(2) Who works with the reporting entity under contract; or

(3) To whom the reporting entity has granted privileges.

B. A reporting entity shall inform the Board of any change that has been made, in whole or in part, because the reporting entity had reason to believe that the health care provider:

(1) Abandoned a patient;

(2) Provided patient care of questionable quality;

(3) Disrupted the workplace;

(4) Committed unethical or unprofessional conduct;

(5) Committed billing or coding fraud;

(6) Used the reporting entity’s employment or privileges to commit illegal or unethical business practices;

(7) Suffers from a physical, a mental, or an emotional condition or impairment that affects the health care provider’s ability to perform the individual’s medical or surgical duties;

(8) Is habitually intoxicated by alcohol or a controlled dangerous substance;

(9) Provided care while under the influence of alcohol or while abusing or misusing any controlled dangerous substance or mood-altering substance;

(10) Has not complied with the requirements of an alcohol or a drug treatment program;

(11) With respect to allied health providers, failed to notify the reporting entity of the health care provider’s decision to enter into an alcohol or a drug treatment program;

(12) Performed care beyond the scope of licensure or privileges or delegated duties, or delegated duties to an individual not authorized to perform those duties;

(13) Repeatedly failed to complete medical records;

(14) Repeatedly violated hospital bylaws, rules, policies, or procedures after warning; or

(15) Committed any other act or suffered from any other condition which the reporting entity had reason to believe may constitute a violation of the Acts.

C. Specific Changes Not Reportable.

The following changes do not require reporting by a reporting entity:

(1) Leaves of absence that:

(a) Are not involuntary leaves of absence as defined in Regulation .02 of this chapter;

(b) Are taken by a health care provider who is in good standing; and

(c) May be caused by, for example:

(i) Maternity leave;

(ii) Family problems of a medical or other personal nature;

(iii) Medical problems that do not implicate the health care provider’s physical, mental, or emotional ability to provide competent care;

(iv) Military deployment;

(v) Sabbaticals;

(vi) Extended vacations; or

(vii) Absences for professional training;

(2) Resignations that:

(a) Are not involuntary resignations as defined in Regulation .02 of this chapter;

(b) Are submitted by a health care provider who is in good standing; and

(c) May be caused by, for example:

(i) A job or career change;

(ii) The health care provider's desire to relocate from Maryland;

(iii) The health care provider's desire to retire; or

(iv) A decision by an individual in a postgraduate training program to leave the program to pursue another specialty before the expiration of the term of the training program originally contemplated;

(3) Alterations in practice that:

(a) Are not involuntary alterations in practice as defined in Regulation .02 of this chapter;

(b) Are submitted by a health care provider who is in good standing; and

(c) May be caused by, for example, a health care provider's desire to:

(i) Switch from active practice to consulting;

(ii) Reduce workload; or

(iii) Alter a specialty or scope of practice;

(4) With respect to allied health providers, the initial denial of employment or privileges;

(5) With respect to physicians, an involuntary alteration in practice that:

(a) Results solely from an FPPE or a focused review;

(b) Does not by itself or in combination with any other involuntary alteration in practice exceed 90 days in any one calendar year;

(c) Consists solely of one or more of the following:

(i) A program of additional training or monitoring or heightened scrutiny of the individual's practice; or

(ii) A requirement that the individual successfully perform a skill, an activity, or a procedure a specific number of times, or within a specific time period; and

(d) Does not result from inappropriate sexual behavior, harassment, or any other unprofessional conduct in the workplace;

(6) With respect to physicians, the initial denial of employment or privileges due solely to the applicant's:

(a) Inability to fulfill on-call requirements because of other time commitments;

(b) Lack of a board certification required by the reporting entity; or

(c) Lack of experience in conducting a particular medical procedure;

(7) Administrative suspensions, if the sum total does not cumulatively exceed 30 days in any one calendar year, imposed on or agreed to by the health care provider, solely for the health care provider's failure to:

(a) Acquire mandated vaccinations or required serum titers for infections;

(b) Attend required meetings;

(c) Complete medical records;

(d) Complete required training; or

(e) Maintain or submit a certificate of professional insurance;

(8) With respect to an individual in a postgraduate training program:

(a) The expiration of the postgraduate training program contract at the end of its term as originally contemplated and while the individual is in good standing with the program; or

(b) Academic probation, unless imposed for any of the reasons set out in §B(3), (4), (8) or (9) of this regulation.

(9) With respect to allied health providers and subject to the requirements of §C(9)(b) and (c) of this regulation:

(a) Entrance into an alcohol or a drug treatment program that is:

(i) Accredited by the Joint Commission;

(ii) Certified by the Department of Health and Mental Hygiene; or

(iii) Provided by a health care practitioner who is competent and capable of dealing with alcoholism and drug abuse.

(b) Section C(9)(a) of this regulation applies only where:

(i) The allied health provider notified the reporting entity at the time the allied health provider decided to enter the program;

(ii) The reporting entity is able to verify that the allied health provider remains continually in the program until properly discharged; and

(iii) The action or condition of the allied health provider had not caused injury to any individual during the provision of health care by the allied health provider.

(c) Section C(9)(a) of this regulation does not apply to:

(i) Any change made by a reporting entity relating to the discharge of an allied health provider from an alcohol or a drug treatment program, when that discharge was for non-attendance or non-compliance with the program;

(ii) Additional changes made by the reporting entity, other than minor scheduling changes made solely to accommodate participation in the program; or

(iii) Any change made by the reporting entity based on events set out in Regulation .03B which occurred subsequent to the provider's entrance into the alcohol or drug treatment program;

(10) With respect to physicians and subject to the requirements of §C(10)(b) and (c) of this regulation:

(a) Entrance into an alcohol or a drug treatment program:

(i) That is accredited by the Joint Commission;

(ii) That is certified by the Department of Health and Mental Hygiene, or

(iii) To which the physician is referred by the Physician's Rehabilitation Program funded by the Board under the Health Occupations Article, §14-401.1(g), Annotated Code of Maryland;

(b) Section C(10)(a) of this regulation applies only where the action or condition of the physician had not resulted in injury to any individual during the provision of health care by the physician.

(c) Section C(10)(a) of this regulation does not apply to:

(i) Any change made by a reporting entity relating to the discharge of a physician by an alcohol or a drug treatment program, when that discharge was for non-attendance or non-compliance with the program;

(ii) Additional changes made by the reporting entity, other than minor scheduling changes made solely to accommodate participation in the program; or

(iii) Any change made by the reporting entity relating to events set out in §B of this regulation which occurred subsequent to the physician's entrance into the alcohol or drug treatment program.

D. With respect to physicians, each reporting entity shall file a report with the Board that contains the name of each licensed physician who, during the six months preceding the report, was employed by, had privileges with, or applied for privileges with that entity.

.04 Naturopathic Doctors.

A. A licensed naturopathic doctor, other licensed health care provider, health care facility located in the State, or State agency shall file a written report to the Board if there is reason to believe that a licensed naturopathic doctor is or may be:

(1) Medically or legally incompetent;

(2) Engaged in the unauthorized practice of naturopathic medicine;

(3) Guilty of unprofessional conduct; or

(4) Mentally or physically unable to engage safely in the practice of naturopathic medicine.

B. The report required under §A of this regulation shall be filed with the Board within 30 days after the individual or entity becomes aware of this information.

C. A health care facility shall report within 10 days to the Board if a licensed naturopathic doctor voluntarily resigns from the staff of the health care facility, voluntarily limits staff privileges, or fails to reapply for hospital privileges at the health care facility while the naturopathic doctor is under formal or informal investigation by the health care facility for possible medical incompetence, unprofessional conduct, or mental or physical impairment.

.05 Timeframes for the Submission of Reports.

A. Physicians or Individuals in a Postgraduate Training Program.

(1) A reporting entity shall file reports required under this chapter with the Board:

(a) Within 10 days of any change made with regard to a physician or an individual in a postgraduate training program; and

(b) Twice a year:

(i) In a cumulative report of all changes made with regard to physicians and individuals in postgraduate training programs; and

(ii) Separately, in the report required under Regulation .03D of this chapter.

(2) Within 10 days, the reporting entity who has reported a change to the Board under this chapter shall report to the Board in writing any modifications made to, or subsequent developments in, that change.

(3) The required reports prescribed in §A(1)(b) of this regulation shall be filed as follows:

(a) By February 1 of each year for the 6-month reporting period of July 1 through December 31 of each year; and

(b) By August 1 of each year for the 6-month reporting period of January 1 through June 30 of each year.

B. Allied Health Providers.

(1) Except as provided in §B(2) of this regulation, a reporting entity shall file any report required under this chapter within 10 days of any change made with respect to allied health providers.

(2) With respect to physician assistants:

(a) An employer of a physician assistant who terminates the physician assistant because of a quality of care issue shall report the termination within 5 days of the termination;

(b) Any person who terminates a delegation agreement with a physician assistant shall report that termination within 10 days; and

(c) A report submitted under §B(2)(b) of this regulation may not be used to fulfill the requirement of §B(2)(a) of this regulation.

C. Naturopathic Doctors.

(1) Within 30 days, a licensed naturopathic doctor, other licensed health care provider, health care facility located in the State, or State agency shall file a written report with the Board upon becoming aware of information described in Regulation .04A of this chapter.

(2) Within 10 days, a health care facility shall report to the Board any information required under Regulation .04C.

.06 Enforcement.

A. The Board shall conduct any necessary investigation regarding failure of a reporting entity to file a report required under this chapter.

B. Over the signature of an officer, the executive director, or the deputy director, the Board may issue subpoenas in connection with any investigation or proceeding to enforce this chapter.

C. Before submission of the final investigative report to the Board, the investigator shall inform the reporting entity of the allegation of failure to report and offer the reporting entity an opportunity to submit a written response. Any written response shall be made part of the investigative report. The investigative report is confidential and may not be released to any person except as provided in §E of this regulation.

D. The final investigative report shall be submitted to the Board. The Board, after consideration of the investigative report, shall:

(1) If it finds probable cause that the reporting entity failed to report as required by this chapter, vote to issue a notice of failure to file a report setting out the facts of the alleged failure and the recommended civil penalty as set out in §O of this regulation; or

(2) Dismiss the case.

E. If the Board votes to issue a notice of failure to file a report, the Board shall mail by first class mail the notice of failure to file a report to the reporting entity involved. Upon this mailing, the Board shall make available to the reporting entity the investigative report, less the names of any confidential informants who will not be called as witnesses in the case.

F. If the reporting entity does not request a hearing within 30 days of the date the notice of failure to file a report was mailed, the notice of failure to file a report shall become final and shall constitute a final disposition of the Board.

G. A reporting entity which has timely filed a request for a hearing may choose to attend a settlement conference with a committee of the Board to attempt to resolve a case. If a settlement conference is convened:

(1) The reporting entity may be represented by counsel;

(2) Except for consideration of a proposed resolution of the case, the Board may not use any commentary, admissions, facts revealed, or positions taken at the settlement conference, unless the subject matter is available from other sources or is otherwise discovered;

(3) At the conclusion of the settlement conference, the committee shall recommend either:

(a) Dismissing the notice of failure to file a report; or

(b) Upholding the notice of failure to file a report and imposing a civil penalty as set out in §O of this regulation.

H. If the reporting entity agrees with the recommendation of the settlement committee, the Board shall consider the recommendation and either accept or reject it. The Board's acceptance of the settlement committee's recommendation constitutes the Board's final disposition of the case.

I. If a settlement is not reached or if the settlement committee's recommendation is not approved by the Board, the case shall proceed to a hearing before the Board.

J. The hearing ordinarily shall be limited to oral argument before the Board. The issues at the hearing are limited to whether a reporting entity:

(1) Made a change as defined in this chapter;

(2) Had reason to believe that the change was made, in whole or in part, because of a reason listed in Regulation .03B of this chapter;

(3) Reported the change to the Board; and

(4) Reported the change within the timeframes set out in this chapter.

K. The Board chair or alternate presiding officer may reasonably limit the time for oral argument.

L. The Board shall conduct an evidentiary hearing if the chair or alternate presiding officer finds that there is a substantial dispute concerning one or more of the material facts set out in §H of this regulation. If there is an evidentiary hearing, the Board chair or alternate presiding officer may:

(1) Administer oaths or affirmations;

(2) Issue subpoenas for relevant evidence;

(3) Make all rulings on the admission of evidence;

(4) Rule on motions;

(5) Exclude repetitive or irrelevant evidence, require the parties to narrow the factual evidence to the relevant issues, and make any other rulings in order to focus and expedite the proceeding;

(6) Require proffers of evidence in advance of the hearing and make evidentiary rulings before the commencement of the hearing; and

(7) Reasonably limit the time for presentations.

M. It is not a defense to the allegation of a failure to report that:

(1) An employee of the reporting entity was not aware of:

(a) The change made by the reporting entity; or

(b) The obligation to report; or

(2) The reporting entity was conducting its own proceeding to further evaluate the change or the reasons for the change.

N. If the Board finds after the hearing that the reporting entity did not fail to file any report required by this chapter, the Board shall issue a final disposition dismissing the notice of failure to file a report.

O. If the Board finds after a hearing that a reporting entity failed to file any report required by this chapter, the Board shall issue a final disposition with findings of fact, conclusions of law, and civil penalty. In its final disposition, the Board may impose a civil penalty as follows:

(1) With respect to reports concerning physicians:

(a) $2,500 for the first occurrence in a calendar year; or

(b) $5,000 for any subsequent occurrence in a calendar year; and

(2) With respect to reports concerning allied health providers:

(a) $500 for the first occurrence in a calendar year; or

(b) $1,000 for any subsequent occurrence in a calendar year.

P. The Board disposition is the final administrative action on the matter.

Q. A reporting entity that is dissatisfied with a final disposition of the Board may seek judicial review of the Board's final disposition as provided in the Administrative Procedure Act. The disposition of the Board may not be stayed pending judicial review.

R. The Board shall pay all monies collected pursuant to this chapter into the State's General Fund. The Board may refer any uncollected civil penalties under this regulation to the Central Collection Unit of the State.

S. The investigative and quasi-judicial procedures set out in this regulation, and the confidentiality provisions of Regulation .08 of this chapter, apply to licensed naturopathic doctors, other licensed health care providers, health care facilities located in the State, and State agencies with respect to any allegations that they failed to file a report required under Regulation .04 of this chapter.

.07 Confidentiality.

A report made to the Board under this chapter is not subject to subpoena or discovery in any civil action other than a proceeding arising out of a hearing and the final disposition of the Board.

.08 Public Notice of Failure to File a Report and Disposition.

A. The notice of failure to file a report and any final disposition under this chapter are public documents.

B. The notice of failure to file a report and any final disposition shall redact:

(1) The name of a patient and any other patient-identifying information; and

(2) Records of a health care provider's or a naturopathic doctor's physical, mental, or emotional condition, except to the extent necessary to identify the deficient practice or condition that caused an entity to make a change as defined in Regulation .02 of this chapter.

.09 Immunity from Civil Liability of Persons.

A person shall have the immunity from liability described under Courts and Judicial Proceedings Article, §5–715(d), Annotated Code of Maryland, for giving any of the information required under Health Occupations Article, §§14-413, 14-414, 14-5A-18, 14-5B-15, 14-5C-18, 14-5E-18, 14-5F-19, or 15-103.

VAN T. MITCHELL

Secretary of Health and Mental Hygiene