PROPOSED RULEMAKING

LIQUOR CONTROL BOARD

[40 PA. CODE CHS. 3, 5 AND 11] Limited Wineries

The Liquor Control Board (Board), under the authority of section 207(i) of the Liquor Code (47 P.S. § 2-207(i)), proposes to delete §§ 3.62—3.64, 5.103 and 11.111, and add §§ 5.401—5.409 to read as set forth in Annex A.

Summary

This proposed rulemaking gathers regulations pertaining to limited wineries from Chapters 3, 5 and 11 (relating to license applications; duties and rights of licensees; and purchases, sales and returns) of the Board's regulations, and places them in a new subchapter in Chapter 5. In addition, this proposed rulemaking revises many of these regulations to make them more consistent with the Liquor Code, which has been amended several times since 2011. The proposed changes are intended to provide more clarity to the regulated community and allow for easier navigation of the applicable regulations.

Currently, regulations that are specifically applicable to licensed limited wineries are located in three different chapters of the Board's regulations: Chapters 3, 5 and 11. The regulated community would benefit from having, in one location, the regulations that apply to them. In addition, the current regulations are out of date and in

Proposed section
Deleted
5.405(c)
5.408
5.409
5.404
5.407
5.407
5.403
5.403
5.402
Deleted
5.406
5.406
5.405, 5.407
5.405(c)
5.409
5.408

Proposed § 5.401 (relating to definitions) is new content; it has not been relocated from another section. The Board believes the addition of these definitions to the regulations will provide clarity. Section 5.401 includes the following:

certain sections, which will be explained as follows, misleading or incorrect. As such, the regulated community, which consists of 450 active licensed limited wineries as of September 3, 2021, will benefit by having accurate, up-to-date regulations.

To ensure that the regulations include only necessary content, two regulations are deleted completely and not relocated. These regulations are §§ 3.62 and 11.111(a)(7) (relating to creation; and sale by limited winery licensees). Section 3.62 states, "Under section 505.2 of the Liquor Code (47 P.S. § 5-505.2), holders of a Limited Winery License may produce and sell wines, subject to §§ 3.63, 5.103 and 11.111 (relating to agents; limited wineries; and sale by limited winery licensees)." It is not necessary to have a regulation reiterate what is provided by statute or other regulations. Similarly, § 11.111(a)(7) provides, "Limited winery licensees engaged in the retail and wholesale sales of wine are responsible to conform to the Liquor Code and this title." It is not necessary to have a regulation that tells the regulated community that they must follow the enabling statute and the regulations.

This proposed rulemaking creates Subchapter K (relating to limited wineries), which incorporates existing regulations from Chapters 3, 5 and 11 and organizes them to improve accessibility for the regulated community. The following two tables show where the previous content has been relocated and a sequential ordering of the new content in Subchapter K, showing its origins:

Proposed section	Current section
5.401	New
5.402	11.111(a)(6)
5.403	11.111(a)(4), (5)
5.404	11.111(a)(1)
5.405	3.63 11.111(a)(10) 11.111(b)
5.406	11.111(a)(8), (9)
5.407	11.111(a)(2)
	11.111(a)(3)
	11.111(a)(10)
5.408	3.64 11.111(d)
5.409	5.103
	11.111(c)

• A definition for "limited winery," which is consistent with the definition provided in section 102 of the Liquor Code (47 P.S. § 1-102), but also incorporates a minimum production amount of 200 gallons per year, based on language in section 491(2) of the Liquor Code (47 P.S.

- § 4-491(2)). Section 491(2) allows the manufacture of up to 200 gallons of wine for personal use without the need to obtain a manufacturing license.
- A definition for "original container," which is based on a definition for the same term that is provided in section 102 of the Liquor Code. However, because the definition in the Liquor Code is geared towards manufacturers of malt or brewed beverages, it has been modified in § 5.401 to apply to limited wineries.
- A definition for "produce" (verb), is proposed to be added because the Board is frequently asked what type of activity is required to say that a limited winery "produced" wine. The need for this definition stems from the following provision in section 505.2(a)(2) of the Liquor Code (47 P.S. § 5-505.2(a)(2)) (emphasis added):
 - [A] limited winery shall not, in any calendar year, purchase alcoholic cider, fermented fruit beverages, mead or wine produced by other limited wineries in an amount in excess of fifty per centum of the alcoholic cider, fermented fruit beverage, mead or wine produced by the purchasing limited winery in the preceding calendar year.
- A definition for "tasting sample," is proposed to be added to provide clarification for \$ 5.402 (relating to tasting samples), addressing where a limited winery may provide tasting samples of winery product. This phrase is added for clarity between the verbiage of the Liquor Code and that of the Board's regulations. The Liquor Code uses the word "samples" to refer to small quantities offered to consumers who want to taste the product. However, in the Board's regulations, "samples" are small bottles of product that may be given to consumers to try at home. See § 13.231 (relating to samples). To reduce confusion, the proposed regulation uses the phrase "tasting sample," which incorporates the verbiage of the Liquor Code but is distinguished from the § 13.231 sample.
- A definition for "wine cooler," is proposed to be added because the phrase appears in the Liquor Code but is not defined in the Liquor Code. The Board had previously attempted to amend the regulations pertaining to limited wineries, (IRRC # 3117, PLCB # 54-85), but the final-form rulemaking was disapproved by the Independent Regulatory Review Commission (IRRC). During that process, IRRC recommended that the Board define the phrase "wine cooler." Based on IRRC's recommendation, the Board is adding a definition to this proposed rulemaking.
- A definition for "winery products," is proposed to be added to enhance the readability of the regulation. It is cumbersome to identify the numerous different products that can be made by a limited winery, including alcoholic cider, fermented fruit beverages, mead, wine or wine coolers, or both. The term "winery products" is an umbrella term that incorporates all of these products. For clarity, the winery products must be produced by the limited winery that is engaging in any of the activities covered by this subchapter.

This proposed rulemaking will add § 5.402 which is based, in part, on the current regulatory provisions in § 11.111(a)(6) of the Board's regulations. Section 11.111(a)(6) states that visitors may be provided samples of wine "without charge." However, section 505.2(a)(4) of the Liquor Code states that samples may be sold or offered free of charge. Therefore, this proposed regulation provides that "The limited winery may provide tasting samples of winery products in accordance with section 505.2(a) of the Liquor Code and § 13.211 (relating to tasting events)." This proposed regulation also provides

that "To the extent possible, section 505.2 of the Liquor Code and § 13.211 will be construed together; however, when there is a conflict between these two sections, including with regard to locations where tasting samples may be provided, the volume of each tasting sample that may be provided, and whether a fee may be charged for a tasting sample, the provisions of section 505.2 of the Liquor Code will prevail." In this way, it is clear that limited wineries may continue offering tasting samples in a manner that is consistent with the provisions of the Liquor Code and the Board's regulations regarding tasting events, depending on the specific circumstances involved with the offering being made.

Section 5.402 clarifies that tasting samples may not be provided at a limited winery's storage facilities. Section 505.2(a)(6.4) of the Liquor Code, allows a limited winery licensee to have up to two Board-approved storage locations. The section provides that only the limited winery licensee and its employees may be present at the storage locations. Therefore, no customers or potential customers should be present at the storage locations, and as a result, no tasting samples may be provided. This section also directs the limited winery licensee to operate the storage locations "under such conditions and regulations as the board may enforce."

This proposed rulemaking will add § 5.403 (relating to sales generally) to give general information regarding sales by a limited winery. This section was based on the current regulation in § 11.111(a)(4). This proposed rulemaking provides that a limited winery may sell winery products during the time periods or circumstances set forth in section 505.2(a)(6.3) of the Liquor Code. In addition, this section incorporates the types of payment that a limited winery may accept, which is currently found in § 11.111(a)(5). A limited winery may accept, from licensees, checks drawn on their account, cash, money orders, cashier checks, debit cards and electronic funds transfers. From unlicensed individuals, a limited winery may accept all of the aforementioned methods as well as credit cards issued by banking or financial institutions subject to Federal or State regulations.

The Board notes that the act of June 8, 2016 (P.L. 273, No. 39) (Act 39 of 2016) specifically amended the Liquor Code to allow distributors and importing distributors to accept credit cards from licensees. No similar amendment was made to allow limited wineries to accept credit cards from licensees. In light of this legislative inaction, the Board decided not to allow limited wineries to accept credit cards for payment by licensees.

Proposed § 5.403 will add language to clarify requirements that exist in the Liquor Code for alcoholic cider, fermented fruit beverages and mead. These products are considered malt or brewed beverages, not wine, and are treated differently under the Liquor Code. For instance, malt or brewed beverages are subject to the brand registration requirements set forth in section 445 of the Liquor Code (47 P.S. § 4-445), as well as the distribution provisions set forth in section 431 of the Liquor Code (47 P.S. § 4-431). This proposed rulemaking explains that a limited winery may sell alcoholic cider, fermented fruit beverages and mead to importing distributors, distributors or any other licensee that is authorized, under the Liquor Code, to sell, possess, or store malt or brewed beverages. However, a limited winery shall not sell wine or wine coolers to importing distributors, distributors or any other licensee that is not authorized, under the Liquor Code, to sell, possess, or store alcoholic beverages other than malt or brewed beverages.

This proposed rulemaking will add § 5.404 (relating to sales for on-premises consumption) which updates the types of liquor or malt or brewed beverages a limited winery may sell for consumption on the premises. Currently, § 11.111(a)(1) of the Board's regulations provides that there may be no consumption of liquor or malt or brewed beverages on the licensed premises. However, the act of June 28, 2011 (P.L. 55, No. 11) (Act 11 of 2011) amended section 505.2(a)(6.1) of the Liquor Code to allow limited wineries to sell, for on-premises consumption, any winery products they could sell for off-premises consumption. In addition, Act 39 of 2016 amended the Liquor Code to allow limited winery licensees to sell malt or brewed beverages and liquor for on-premises consumption, provided that the malt or brewed beverages and liquor are produced by Pennsylvania-licensed manufacturers.

Proposed subsection (c) requires that, if the limited winery licensee sells malt or brewed beverages through a malt or brewed beverage dispensing system—also known as a draft beer system—the limited winery must comply with §§ 5.51—5.54 (relating to cleaning of malt or brewed beverage systems). The limited winery licensee will be held to the same standard of beer line cleaning as other retail dispensers who sell beer by draft. In addition, proposed subsection (d) provides that a limited winery that chooses to sell wine or wine coolers through a wine dispensing system must comply with § 11.103 (relating to dispensing system sanitation).

Proposed § 5.405 (relating to sales for off-premises consumption) pertains to sales for off-premises consumption. This section begins with a reference to section 505.2(a) of the Liquor Code. Subsection (b) is based on current § 11.111(a)(10) and has been expanded to allow the acceptance of orders by the Internet. Subsection (b) references proposed § 5.407 (relating to delivery of products). Subsection (c) incorporates the regulatory language regarding agents, which is currently located in § 3.63 (relating to agents). Subsections (d) and (e) clarify who may sell winery products at wine expositions and farmers markets, as well as where those sales must occur.

Proposed § 5.406 (relating to sales of other items) updates the list of items that limited wineries may sell. Currently found in § 11.111(a)(8), the list is amended to reflect the statutory changes found in section 505.2(a)(6.1) and (6.2) of the Liquor Code. Act 11 of 2011 amended section 505.2(a)(6.1), which now permits limited winery licensees to "Sell food for consumption on or off the licensed premises. . . . "The statute does not authorize any restriction as to the source or type of food. Thus, the current reference to fruits, jellies, jams, preserves and mushrooms, as well as cheese, crackers, breads, nuts and preserved meats, is most since each of these items is permissible under the limited winery's general authority to sell food. Proposed § 5.406 also incorporates current § 11.111(a)(9), which explains the process for a limited winery to follow if it wants to sell something that is not on the regulatory list.

Proposed § 5.407 (relating to delivery of products) sets forth rules pertaining to the delivery of winery products by or for limited wineries. Subsection (a) identifies general rules for all deliveries by a limited winery. Subsection (b) pertains to a limited winery utilizing its own vehicles to deliver its winery products, whereas subsection (c) pertains to a limited winery utilizing a transporter-for-hire licensee to delivery its winery products.

Subsection (d) addresses a change in the law regarding the delivery of wine or wine coolers to an unlicensed individual. Act 39 of 2016 amended the Liquor Code to require limited winery licensees—and all other wine manufacturers—to obtain a direct wine shipping license before shipping wine to consumers in this Commonwealth. Subsection (d) clarifies that the delivery of alcoholic cider, fermented fruit beverages or mead, does not require a direct wine shipping license. Finally, subsection (e) incorporates language from current § 11.111(a)(10), that limited wineries are responsible for ensuring that winery products are not delivered to minors or visibly intoxicated persons, and that proper receipts are provided in accordance with § 5.409 (relating to records, receipts and reports).

Proposed § 5.408 (relating to additional Board-approved locations) is largely based on current § 3.64 (relating to additional Board-approved locations). Subsection (e) refers licensees to four other sections in the Board's regulations—§§ 3.51 through 3.54—and was included to reduce confusion among licensees as to what may or may not be an appropriate location for an additional Board-approved location. Subsections (j) and (k) offer new guidance to clarify to licensees what arrangements are and are not consistent with the Liquor Code when multiple licensees want to operate additional Board-approved locations.

Proposed § 5.409 is based substantially upon current § 5.103 (relating to records, invoices and reports). The term "invoices" has been amended with "receipts" because it is a more accurate term to describe the paperwork that accompanies a purchase of a winery product. Invoices are issued prior to payment; receipts are issued after payment. A licensee cannot sell products off of the licensed premises; therefore, there should never be a situation where a product is shipped with an invoice for the recipient to pay after the product is received. A licensee can only ship products for which payment has already been received. That being the case, the proper terminology for the document that accompanies the product is "receipt," not "invoice."

In proposed \S 5.409, current \S 5.103(a) was broken into subsections for easier comprehension. The phrase "agricultural commodity" replaces the word "fruits" to be consistent with section 505.2(a)(1) of the Liquor Code. The last sentence of current \S 5.103(a) is deleted since it is actually a repeat of a sentence that occurs earlier in that section.

Proposed subsection (b) is based on current § 5.103(b) and addresses receipts and identifies what information the sales receipt should include. Proposed subsection (c) is based on current § 5.103(b)(5) and sets forth how receipts are to be used during a delivery. Proposed subsection (d) pertains to reports and is based on the text at current § 5.103(c) but broken into paragraphs and subparagraphs for greater readability.

Affected Parties

The affected parties include present and future holders of a limited winery license. As of September 3, 2021, there are approximately 450 active limited winery licensees that could be affected by this proposed rulemaking.

Paperwork Requirements

This proposed rulemaking would not require any additional paperwork to be filed.

Fiscal Impact

The proposed regulatory changes are intended to make the Board's regulations consistent with the Liquor Code. Therefore, no fiscal impact is anticipated. Effective Date

This proposed rulemaking will become effective upon final-form publication in the *Pennsylvania Bulletin*.

Public Comments

Interested persons are invited to submit written comments about this proposed rulemaking to Rodrigo Diaz, Chief Counsel, Jason M. Worley, Deputy Chief Counsel, or Norina Foster, Assistant Counsel, Office of Chief Counsel, Liquor Control Board, Room 401, Northwest Office Building, Harrisburg, PA 17124-0001, or RA-lblegal@pa.gov, within 30 days after publication of this proposed rulemaking in the *Pennsylvania Bulletin*. E-mail is preferred. When commenting, individuals should indicate if they wish to be apprised of future developments regarding this proposed rulemaking, and include a name, address and e-mail address. Comments submitted by facsimile will not be accepted.

Public comments will be posted on IRRC's web site. Personal information will not be redacted from the public comments received.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. §§ 745.5(a)), on November 9, 2021, the Board submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to IRRC and to the Chairpersons of the House Liquor Control Committee and Senate Committee on Law and Justice. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey comments, recommendations or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections must specify the regulatory review criteria in section 5.2 of the Regulatory Review Act (71 P.S. § 745.5b) which have not been met. The Regulatory Review Act specifies detailed procedures for review prior to final publication of the rulemaking by the Board, the General Assembly and the Governor.

TIM HOLDEN, Chairperson

Fiscal Note: 54-95. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 40. LIQUOR

PART I. LIQUOR CONTROL BOARD CHAPTER 3. LICENSE APPLICATIONS

Subchapter G. [LIMITED WINERY LICENSES] (Reserved)

§ 3.62. [Creation] (Reserved).

[Under section 505.2 of the Liquor Code (47 P.S. § 5-505.2), holders of a Limited Winery License may produce and sell wines, subject to §§ 3.63, 5.103 and 11.111 (relating to agents; limited wineries; and sale by limited winery licensees).]

§ 3.63. [Agents] (Reserved).

A limited winery licensee may employ individuals to solicit orders, off the licensed premises, for wine produced by it or to promote the sale of wine off the premises. Agents may advertise and promote the sale of merchandise by "missionary work" of only brands sold by the limited winery licensee by

whom the agents are employed and may solicit orders from licensees and make deliveries in properly registered vehicles.]

- § 3.64. [Additional Board-approved locations] (Reserved).
- [(a) Additional locations, as authorized by section 505.2(3) of the Liquor Code (47 P.S. § 5-505.2(3)) may not be used by a limited winery licensee in the operation of a licensed business unless approved by the Board.
- (1) An application for an additional location shall be made to the Board, accompanied by a \$220 fee. A renewal application shall be submitted annually and be accompanied by a \$75 fee.
- (2) Applications for additional Board-approved locations may be submitted on a prior approval basis. If plans are approved, the necessary construction or alterations shall be completed within 6 months of the approval. Business may not be transacted until the premises has been reinspected and the Board has approved the completed construction or alterations.
- (3) Portions of an additional Board-approved location premises shall be contiguous.
- (4) Additional Board-approved locations of a limited winery license shall be under the control of a manager appointed in accordance with § 5.16 (relating to appointment of managers).
- (5) Additional Board-approved locations of a limited winery license shall be enclosed by soundly constructed walls, with controlled points of access and egress directly accessible to the general public from a public thoroughfare.
- (6) Limited winery licensees shall provide Board officers conducting licensing investigations of additional locations with the following:
 - (i) Leases which contain percentage agreements.
 - (ii) Management agreements.
 - (iii) Employe agreements.
 - (iv) Commission agreements.
- (b) Limited winery licensees shall notify the Board immediately upon discontinuing use of an additional location.]

CHAPTER 5. DUTIES AND RIGHTS OF LICENSEES

Subchapter H. RECORDS AND REPORTS—BREWERIES, BONDED WAREHOUSES, [LIMITED WINERIES] AND LICENSED DISTILLERIES OF HISTORICAL SIGNIFICANCE

§ 5.103. [Limited wineries] (Reserved).

[(a) Records. A holder of a Limited Winery License obtained under § 3.62 (relating to creation) shall maintain and keep on the licensed premises daily permanent records which shall conform to the requirements of section 512 of the Liquor Code (47 P.S. § 5-512). The records shall include complete details concerning the source of fruits used in the production of wines. Electronic media recordkeeping, maintained and based upon generally accepted accounting principles, shall be permitted in lieu of hard copy records. The recordkeeping system utilized by the licensee shall have the capability to

provide for the reconciling of required data. Entries shall be verifiable by supporting original documents. The records shall include complete details concerning the source of fruits used in the production of wines.

- (b) Sales invoice. In addition to the records prescribed in subsection (a), except as otherwise provided in this part, a sales invoice shall be prepared at the licensed premises for each sale. The sales invoice shall be prepared in accordance with the following:
- (1) The sales invoice shall be imprinted or affixed with the name and address of the limited winery.
- (2) The sales invoice shall show the name and address of the recipient of the merchandise, date of sale, number of units, size and type of package, brand name, selling price of the wine and the net cost to the customer. The name and address of private individuals is not required on sales invoices covering quantities of 16 liters or less; in lieu of preparing sales invoices for the sales, the transactions may be entered individually on a counter sheet maintained in columnar form showing the information required on sales invoices, other than name and address of the purchaser. The counter sheet shall be totaled daily and the totals entered into the sales register noted in section 512 of the Liquor Code (47 P.S. § 5-512).
- (3) The sales invoice shall show the Commonwealth sales tax, where applicable, as a separate entry.
- (4) The sales invoice may include other items permitted for sale by limited wineries if the sale of wines is listed separately from other permitted items sold by the licensee.
- (5) An invoice shall be prepared for any amount of wine shipped to customers via Transporter-for-Hire, Class C carriers. The invoice shall be prepared only for persons 21 years of age or older, and limited winery licensees shall request the signature of a recipient, 21 years of age or older, from the transporter making the deliveries and a return acknowledgement of delivery to the recipient. Copies of acknowledgments of delivery shall be maintained on the licensed premises for 2 years.
- (6) When a sale requires the preparation of an invoice, one copy shall be given to the recipient of the merchandise and a copy retained on the licensed premises for 2 years.
- (c) Reports. A licensed limited winery shall file reports in the manner set forth by the Board covering operations of their licensed business during the preceding calendar year. The reports shall be signed and sworn to by the licensee or his authorized agent and shall be filed with the Board at the time of the renewal or validation of the license. A copy of each report shall be retained on the licensed premises for at least 2 years from the date of filing. Failure to file the reports will preclude the Board from renewing or validating the license in question. These reports are in addition to information or reports the licensed limited winery may be required to provide to the Department of Agriculture under 3 Pa.C.S. Chapter 45 (relating to Agricultural Commodities Marketing Act) and regu-

lations promulgated thereunder, including 7 Pa. Code § 104.75 (relating to accounting and payment).

(*Editor's Note*: The following subchapter is proposed to be added and is printed in regular type to enhance readability.)

Subchapter K. LIMITED WINERIES

Sec.	
5.401.	Definitions.
5.402.	Tasting samples.
5.403.	Sales generally.
5.404.	Sales for on-premises consumption.
5.405.	Sales for off-premises consumption.
5.406.	Sales of other items.
5.407.	Delivery of products.
5.408.	Additional Board-approved locations.
5.409.	Records, receipts and reports.

§ 5.401. Definitions.

The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise:

Limited winery—A winery that produces at least 200 gallons per year but not more than 200,000 gallons per year of winery products for each full calendar year that the limited winery holds an active limited winery license from the Commonwealth.

Original container—All bottles, casks, kegs, cans, boxes or other suitable containers that have been securely capped, sealed or corked by the limited winery at the place of manufacture, with the name and address of the limited winery affixed to the bottle, cask, keg or other container.

Produce—To manufacture winery products from agricultural commodities, including preparation for fermentation, fermentation, blending, preserving, filtering and packaging the winery products.

Tasting sample—An individual portion of a winery product, in an open container, offered to allow a consumer to sample the flavor of the winery product.

Wine cooler—A beverage made from combining wine with a non-alcoholic beverage, such as fruit juice or a carbonated beverage, resulting in a beverage with lower alcohol by volume than the original wine, and shall not include a malt or brewed beverage.

Winery products—All alcoholic products including alcoholic cider, fermented fruit beverages, mead, wine and wine coolers that have been produced by the limited winery.

§ 5.402. Tasting samples.

- (a) A limited winery may provide tasting samples of winery products in accordance with section 505.2(a) of the Liquor Code (47 P.S. § 5-505.2(a)) and § 13.211 (relating to tasting events). To the extent possible, section 505.2 of the Liquor Code and § 13.211 shall be construed together; however, when there is a conflict between these two sections, including with regard to locations where tasting samples may be provided, the volume of each tasting sample that may be provided and whether a fee may be charged for a tasting sample, the provisions of section 505.2 of the Liquor Code shall prevail.
- (b) Tasting samples may not be provided at a limited winery's storage facilities since only the limited winery and its employees may be present at those locations, in accordance with section 505.2(a)(6.4) of the Liquor Code.

§ 5.403. Sales generally.

- (a) A limited winery may sell winery products during the time periods or circumstances set forth in section 505.2(a)(6.3) of the Liquor Code (47 P.S. § 5-505.2(a)(6.3)).
- (b) A limited winery may accept all of the following methods of payment:
- (1) From licensees: checks drawn on their account, cash, money orders, cashier checks, debit cards and electronic funds transfers.
- (2) From unlicensed individuals: all of the methods of payment listed in paragraph (1) and credit cards issued by banking or financial institutions subject to Federal or State regulations.
- (c) A limited winery that manufactures alcoholic cider, fermented fruit beverages and mead, which are defined as "malt or brewed beverages" in section 102 of the Liquor Code (47 P.S. § 1-102), must register these brands with the Board as required under section 445 of the Liquor Code (47 P.S. § 4-445). The following apply:
- (1) A limited winery may self-distribute alcoholic cider, fermented fruit beverages and mead to importing distributors, distributors or any other licensee that is authorized under the Liquor Code to sell, possess or store malt or brewed beverages.
- (2) A limited winery may choose to grant territorial distribution rights and name a distributor or an importing distributor as the primary or original supplier of the product in accordance with section 431(b) of the Liquor Code (47 P.S. § 4-431(b)).
- (d) A limited winery may not sell wine or wine coolers to importing distributors, distributors, retail dispensers or any other licensee that is not authorized under the Liquor Code to sell, possess, or store any alcoholic beverages other than malt or brewed beverages.

§ 5.404. Sales for on-premises consumption.

- (a) A limited winery may sell winery products on the licensed premises and at additional Board-approved locations in accordance with the Liquor Code and this part. Sales of winery products for on-premises consumption may be made by the glass, bottle or any other open or closed container.
- (b) A limited winery may sell, only for on-premises consumption, malt or brewed beverages and liquor produced by Pennsylvania-licensed manufacturers, under section 505.2(a)(6.1) of the Liquor Code (47 P.S. § 5-505.2(a)(6.1)).
- (c) A limited winery that chooses to sell malt or brewed beverages through a malt or brewed beverage dispensing system, defined in § 5.50 (relating to definition), must comply with §§ 5.51—5.54 (relating to cleaning of malt or brewed beverage systems).
- (d) A limited winery that chooses to sell wine or wine coolers through a wine dispensing system must comply with § 11.103 (relating to dispensing system sanitation).

§ 5.405. Sales for off-premises consumption.

(a) A limited winery may sell winery products for off-premises consumption as permitted under section 505.2(a) of the Liquor Code (47 P.S. § 5-505.2(a)).

- (b) A limited winery may accept orders for the purchase of its winery products in person or through mail, telephone or the Internet. A limited winery shall make deliveries of winery products in accordance with § 5.407 (relating to delivery of products).
- (c) A limited winery may employ individuals, known as agents, to solicit orders for winery products or promote the sale of winery products. The following apply:
- (1) Agents may only advertise and promote the sale of winery products produced by the limited winery that has employed the agent. Agents may solicit orders from licensees and make deliveries on behalf of the limited winery in accordance with § 5.407.
- (2) Agents may only sell, as that word is defined under section 102 of the Liquor Code (47 P.S. § 1-102), the limited winery's products on the limited winery's licensed premises, additional Board-approved location or a location that is covered by the limited winery's wine exposition permit or farmer's market permit.
- (d) Under section 505.2(a)(4) of the Liquor Code, a limited winery may obtain a permit to participate in alcoholic cider, fermented fruit beverages, mead, wine and food expositions off the licensed premises. The following apply:
- (1) Only the limited winery, including its employees and agents, may sell its winery products at a wine and food exposition.
- (2) Sales of the limited winery's products must occur on a location within the exposition that is covered by the limited winery's wine exposition permit.
- (e) Under section 505.2(a)(4.1) of the Liquor Code, a limited winery may obtain a permit to participate in one or more farmers' markets at any given time and an unlimited number throughout the year. The following apply:
- (1) Only the limited winery, including its employees and agent, may sell its winery products at a farmers market
- (2) Sales of the limited winery's products must occur on a location within the farmers market that is covered by the limited winery's farmers market permit.

§ 5.406. Sales of other items.

- (a) In addition to the sale of food, wine-scented or liquor-scented candles, and any other item authorized under section 505.2(a) of the Liquor Code (47 P.S. § 5-505.2(a)), the following items are permitted to be offered for sale on the licensed premises and at additional Board-approved locations:
- (i) Home winemaking, cider making, fermented fruit beverage making or mead making equipment, or both and supplies.
- (ii) Serving and storage accessories as follows: cork removers, wine glasses and decanters, wine racks, serving baskets and buckets and bottle stoppers.
- (iii) Publications dealing with wine and winemaking, alcoholic cider and cider making, fermented fruit beverages and fermented fruit beverage making and mead and mead making.
- (iv) Promotional items advertising the limited winery including tee shirts, glassware, caps and the like.

(b) If a limited winery wants to sell on the licensed premises or additional Board-approved location an item that is not listed in subsection (a), the limited winery shall request, in writing, Board approval to sell that item. The Board will advise the limited winery, in writing, whether approval to sell the item is granted, with or without conditions, or denied.

§ 5.407. Delivery of products.

- (a) The only winery products a limited winery is authorized to deliver are those it has produced. A limited winery may not deliver any liquor or malt or brewed beverages, as those terms are defined in section 102 of the Liquor Code (47 P.S. § 1-102), that were manufactured by another entity. The following apply:
- (1) A limited winery shall ensure that winery products sold and delivered to points within this Commonwealth are sealed in original containers and labeled as required by applicable law.
- (2) A limited winery may deliver food or other nonalcoholic items that have already been purchased by the customer. A limited winery may not offer for sale items from the delivery vehicle.
- (3) A limited winery shall include with the delivery of any winery products a sales receipt in accordance with § 5.409(b) (relating to records, receipts and reports).
- (b) A limited winery may utilize its own vehicle to deliver its winery products. The following apply:
- (1) A limited winery's vehicle must be identified in accordance with § 9.22 (relating to identification of vehicles).
- (2) A limited winery may utilize the same vehicle to deliver alcoholic cider, fermented fruit beverages or mead as well as wine or wine coolers.
- (c) A limited winery may utilize a transporter-for-hire licensee to deliver its winery products. The following apply:
- (1) Alcoholic cider, fermented fruit beverages and mead may be delivered by a Transporter-for-Hire Class A, B or C, in accordance with §§ 9.1 and 9.11 (relating to definitions; and transportation-for-hire).
- (2) Wine or wine coolers must be delivered by a Transporter-for-Hire Class A or Class C, but may not be delivered by a Transporter-for-Hire Class B, in accordance with §§ 9.1 and 9.11.
- (d) Prior to delivering wine or wine coolers to an unlicensed individual in this Commonwealth, a limited winery shall obtain a direct wine shipping license under section 488 of the Liquor Code (47 P.S. § 4-488). The following apply:
- (1) A direct wine shipping license is required whether the delivery of wine or wine coolers is accomplished by the limited winery or by a transporter-for-hire.
- (2) A direct wine shipping license is not required for the lawful delivery of wine or wine coolers to another licensee, or for the lawful delivery of alcoholic cider, fermented fruit beverages or mead.
- (e) It is the limited winery's responsibility to ensure that its winery products are not delivered to minors or visibly intoxicated persons and that proper receipts are provided under § 5.409.

§ 5.408. Additional Board-approved locations.

- (a) A limited winery may not use additional locations, as authorized under section 505.2(a)(3) of the Liquor Code (47 P.S. § 5-505.2(a)(3)), in the operation of a licensed business unless the additional location is approved by the Roard
 - (b) Applications and fees are as follows:
- (1) A limited winery seeking Board approval of an additional location shall submit an application to the Board, accompanied by payment of a \$220 fee. Board approval is valid for that calendar year.
- (2) If a limited winery wants to continue use of the additional Board-approved location, it shall submit a renewal application on an annual basis, accompanied by payment of a \$75 fee.
- (c) If the additional location requires physical alterations or new construction, the Board may grant prior approval for the additional location, as similarly provided in section 403(a) of the Liquor Code (47 P.S. § 4-403(a)). The limited winery may not produce or sell any winery products at the location until the additional location has been re-inspected and the Board has approved the completed alterations or construction and issued the limited winery a license for the additional location.
- (d) Portions of an additional Board-approved location must be contiguous.
- (e) The licensed premises and any additional Board-approved locations of a limited winery are subject to the following regulations:
 - (1) § 3.51 (relating to connection with residence);
 - (2) § 3.52 (relating to connection with other business);
- (3) § 3.53 (relating to restriction on storage and sales where Board has approved connection with other business); and
- (4) § 3.54 (relating to separation between licensed premises and other business).
- (f) The limited winery shall appoint a manager for each additional Board-approved location in accordance with § 5.23 (relating to appointment of managers).
- (g) Additional Board-approved locations of a limited winery license shall be enclosed by soundly constructed walls, with controlled points of access and egress directly accessible to the general public. The application shall be subject to the provisions of section 468(e)(2) of the Liquor Code (47 P.S. § 4-468(e)(2)).
- (h) A limited winery shall provide Board officers who are conducting licensing investigations of additional locations with all of the following:
- (1) Leases or other evidence of the right to occupy the premises.
 - (2) Management agreements.
 - (3) Employee agreements.
 - (4) Commission agreements.
- (5) Any other agreement the Board may deem necessary.

- (i) The Board may grant permission for two or more limited wineries to share a single, additional Board-approved location, in accordance with section 505.2(a)(3) of the Liquor Code.
- (j) The Board shall not grant permission for a limited winery and another manufacturer, such as a brewery, limited distillery or distillery, to share a single, additional Board-approved location.
- (k) If a limited winery licensee holds, under identical ownership, a manufacturing license other than a limited winery license, such as a brewery, limited distillery or distillery license, each licensee may have an additional Board-approved location at the same property, but each licensee shall have its own separate designated area at the property.
- (l) If a limited winery discontinues use of an additional Board-approved location, it shall notify the Board within 15 days of the discontinuance.

§ 5.409. Records, receipts and reports.

- (a) A limited winery shall maintain and keep on the licensed premises daily permanent records that shall conform to the requirements of section 512 of the Liquor Code (47 P.S. § 5-512). The following apply:
- (1) The records shall include complete details concerning the source of any agricultural commodity, as that term is defined in section 505.2(c) of the Liquor Code (47 P.S. § 5-505.2(c)), used in the production of limited winery products.
- (2) Electronic media recordkeeping, maintained and based upon generally accepted accounting principles, may be kept instead of hard copy records.
- (3) The recordkeeping system utilized by the limited winery shall have the capability to provide for the reconciling of required data.
- (4) Entries shall be verifiable by supporting original documents.
- (b) In addition to the records prescribed in subsection (a), the limited winery shall prepare a sales receipt at the licensed premises for each sale to a private individual when the purchase is for greater than 16 liters in a single transaction. The sales receipt shall include all of the following:
 - (1) The name and address of the limited winery.
- (2) The name and address of the recipient of the winery products if the winery products are being delivered off the licensed premises to the recipient.
- (3) The winery products' name, the date of sale, the size of the package in milliliters, number of units sold, the price per unit of the winery products, the Commonwealth sales tax and any other taxes applicable, and the total amount paid by the customer.
- (4) Any items other than winery products that are sold by the limited winery, which shall be listed on the receipt separately from the winery products.
- (c) Any winery products that are delivered shall be accompanied by two copies of a sales receipt that includes the information identified in subsection (b)(1)—(4). The limited winery shall require the person who is delivering the winery products to obtain the signature of the recipient, 21 years of age or older, on one copy of the sales receipt.
- (1) The person delivering the winery products shall give an unsigned copy of the sales receipt to the recipient

- of the winery products and shall retain the signed copy of the sales receipt on the licensed premises for 2 years
- (2) Delivery shall be accomplished in accordance with \S 5.407 (relating to delivery of products).
- (d) A limited winery shall file reports, in the manner set forth by the Board, covering operations of their licensed business during the preceding calendar year. The following apply:
- (1) The reports shall be signed and sworn to by the limited winery or his authorized agent and shall be filed with the Board at the time of the renewal or validation of the license. The following apply:
- (i) A copy of each report shall be retained on the licensed premises for at least 2 years from the date of filing.
- (ii) Failure to file the reports will preclude the Board from renewing or validating the license in question.
- (2) These reports are in addition to information or reports the limited winery may be required to provide to the Department of Agriculture under 3 Pa.C.S. Chapter 45 (relating to Agricultural Commodities Marketing Act) and regulations promulgated thereunder, including 7 Pa. Code § 104.75 (relating to accounting and payment), as well as any reports required under section 488.1 of the Liquor Code (47 P.S. § 4-488.1).

CHAPTER 11. PURCHASES, SALES AND RETURNS Subchapter C. WINES

[LIMITED WINERIES]

- § 11.111. [Sale by limited winery licensees] (Reserved).
- [(a) A limited winery licensee, licensed under § 3.62 (relating to creation), may sell wines produced on the licensed premises in accordance with the Liquor Code and this part, under the conditions in this subsection.
- (1) There may be no sales for consumption on the licensed premises.
- (2) Wine sold under a limited winery license may be shipped by transporter-for-hire or in a vehicle properly registered with the Board, as provided in Chapter 9, Subchapter A (relating to transportation of liquor, malt or brewed beverages or alcohol).
- (3) Wine sold and destined to points within this Commonwealth shall be in sealed original containers.
- (4) Sales may be made generally only between the hours of 9 a.m. and 9 p.m. Monday to Saturday, inclusive, and 10 a.m. to 6 p.m. on Sunday. During the period from the Thanksgiving Day holiday through New Year's Day, limited winery sales locations may remain open until 10 p.m. of sales day to conform with the closing times of neighboring mall or shopping district businesses. Additionally, a limited winery may request approval from the Board to extend sales hours in individual locations at other times during the year, or beyond the limits set in this section. The request shall be in writing, to the Board's Office of the Chief Counsel, and shall detail the exact locations where sales hours are proposed to be extended. The licensee shall also set forth the proposed hours and dates of extended operation, as well as the reason for, and justification of, the proposed extended sales hours.

- (5) While there may be no sales on credit, a limited winery may accept:
- (i) From licensees and retail customers, checks drawn on their account.
- (ii) From retail customers, credit cards issued by banking or financial institutions subject to State or Federal regulations.
- (6) Visitors on the licensed premises may be provided without charge with samples of wine produced by the limited winery for tasting and with crackers, nuts, cheese, bread sticks and bread cubes to be used in conjunction with tastings.
- (7) Limited winery licensees engaged in the retail and wholesale sales of wine are responsible to conform to the Liquor Code and this title.
- (8) In addition to the sale of wines, the following items are permitted to be offered for sale on the licensed premises:
- (i) Pennsylvania-grown fruits and the following products produced from the fruits:
 - (A) Juices.
 - (B) Juice concentrates.
 - (C) Jellies, jams and preserves.
 - (ii) Pennsylvania-grown mushrooms.
 - (iii) Home winemaking equipment and supplies.
- (iv) Wine serving and storage accessories as follows:
 - (A) Cork removers.
 - (B) Wine glasses and decanters.
 - (C) Wine racks.
 - (D) Serving baskets and buckets.
 - (E) Bottle stoppers.
- (v) Publications dealing with wine and winemaking.
- (vi) Cheese, crackers, breads, nuts and preserved meats for consumption off the premises.
- (vii) Gift packages consisting of any combination of the items listed in subparagraphs (i)—(vi).
- (viii) Promotional items advertising the limited winery such as tee shirts, glassware, caps and the like.
- (9) Sales on the licensed premises of merchandise not listed in paragraph (8) is subject to Board approval. The approval shall be requested by letter addressed to the Board. A limited winery licensee will be advised of approved items through an appropriate means of dissemination.
- (10) Mail or telephone orders may be accepted. Delivery of products shall be accomplished through the use of vehicles properly registered by the limited winery licensees or through properly licensed transporters. It is the responsibility of the limited winery licensee to insure that wine is not delivered to minors and that proper invoices are maintained under § 5.103 (relating to limited wineries).
- (b) The employment of an agent by a limited winery is governed by § 3.63 (relating to agents).
- (c) Records, sales invoices and reports shall be kept as prescribed in § 5.103.

(d) The use of additional Board-approved locations by limited winery licensees is governed by § 3.64 (relating to additional Board-approved locations).

[Pa.B. Doc. No. 21-2111. Filed for public inspection December 17, 2021, 9:00 a.m.]

STATE BOARD OF MEDICINE

[49 PA. CODE CHS. 16 AND 18] Registration of Naturopathic Doctors

The State Board of Medicine (Board) proposes to amend Chapters 16 and 18 (relating to State Board of Medicine—general provisions; and State Board of Medicine—practitioners other than medical doctors) to read as set forth in Annex A. Specifically, the Board is proposing amendments to §§ 16.1, 16.11—16.13, 18.13a, 18.15, 18.15a, and the addition of Subchapter M (relating to registration of naturopathic doctors) to Chapter 18 by adding §§ 18.901—18.913.

Effective Date

The proposed amendments will be effective upon publication of the final-form rulemaking in the *Pennsylvania Bulletin*.

Statutory Authority

The primary statutory authority to regulate the registration of naturopathic doctors is the Naturopathic Doctor Registration Act (NDRA) (63 P.S. §§ 272.101—272.301). Specifically, section 207 of the NDRA (63 P.S. § 272.207) provides that "[t]he board shall enforce and administer the provisions of this act and shall promulgate regulations that are consistent with the intent of this act." Further, section 203(b) of the NDRA (63 P.S. § 272.203(b)), provides the authority of the Board to require naturopathic doctor registrations to be renewed "...in a manner and at such intervals as the board shall determine by regulation..." Sections 202(6) and 203(c) of the NDRA (63 P.S. §§ 272.202(6)), set forth the authority of the Board to set fees for initial registration and biennial renewal of registration. The Board sets all fees by regulation.

The Board is taking this opportunity to update its regulations and to remove outdated provisions in the Board's existing regulations relating to "drugless therapists" under the authority of section 8 of the Medical Practice Act of 1985 (act) (63 P.S. § 422.8), which provides, in part, that, "[t]he board, in the exercise of its duties under this act, shall have the power to adopt such regulations as are reasonably necessary to carry out the purposes of this act." This authority necessarily includes the power to repeal provisions of the regulations that are no longer necessary.

Background, Need for and Description of the Proposed Amendments

The Board proposes to amend § 16.1 (relating to definitions) to update the definitions of "act" and "Board-regulated practitioner." The definition of "act" is being amended to update the citation to the Medical Practice Act of 1985 (63 P.S. §§ 422.1—422.53). The definition of "Board-regulated practitioner" is being amended to delete references to "drugless therapists" and add several license classifications which are currently missing from the definition. Specifically, the licensure classifications of

respiratory therapist, genetic counselor, prosthetist, orthotist, pedorthist, orthotic fitter and naturopathic doctor would be added to the definition of "Board-regulated practitioner" in § 16.1. Persons applying for a registration issued by the Board would also be included in the definition of "Board-regulated practitioner."

Additionally, this proposed rulemaking will delete all regulatory references to "drugless therapists." The Board last issued a new license to practice as a drugless therapist in 1951 (1 month after the State Board of Chiropractic began operations) and no longer has the authority to issue new drugless therapist licenses. See Reisinger v. Com., State Bd. of Med. Ed. & Licensure, 399 A.2d 1160 (Pa. Cmwlth. 1979). Reisinger involved an individual trained as a chiropractor and naturopathic doctor who petitioned for licensure as a "drugless therapist," but was denied because the Board determined that it no longer had the authority to license drugless therapists. On appeal, the Commonwealth Court agreed, holding that although the Board could continue to register and regulate persons engaged in the practice of drugless therapy, "the Board lacks the authority now to license Drugless Therapists." See id, 399 A.2d at 1163. Since 1951, the Board has continued to biennially register/ renew existing drugless therapist licenses and has continued to regulate their practice, but has not issued new licenses. No individual currently holds an active license as a drugless therapist from the Board. The last remaining individual who held an active license as a drugless therapist did not renew his license in 2016 and it is the Board's understanding that he died in December of 2014, shortly after submitting his renewal application for the 2015-2016 renewal period. The prior two most recent licensees of the Board last renewed their licenses in 2008. Therefore, it appears that all individuals who held a license as a drugless therapist have either retired from practice or are deceased. Therefore, it is no longer necessary to keep any references to drugless therapists in the Board's regulations. This is especially true now that the Board will be registering individuals as naturopathic doctors under this proposed rulemaking.

As such, the Board proposes to amend § 16.11 (relating to licenses, certificates and registrations) to delete the reference to biennial registration of a drugless therapist license, and add the initial registration as a naturopathic doctor and the biennial registration of a naturopathic doctor. Section 16.12 (relating to general qualifications for licenses and certificates) is proposed to be amended to update its title and to extend its provisions to initial registrations issued by the Board. In addition, the fees associated with biennial renewal of the drugless therapist license are proposed to be deleted from § 16.13 (relating to licensure, certification, examination and registration fees), and the fees associated with naturopathic doctor registration, including the proposed initial registration fee of \$100 and biennial registration renewal fee of \$50, are being added.

Next, the Board proposes amendments to Chapter 18, Subchapter B (relating to the registration and practice of acupuncturists and practitioners of Oriental medicine) to address the overlap between the practice of a naturopathic doctor and an acupuncturist or practitioner of Oriental medicine. Specifically, §§ 18.13a and 18.15a (relating to requirements for licensure as a practitioner of Oriental medicine; and scope of practice of acupuncturists and practitioners of Oriental medicine) are being amended to point out that these regulations do not limit the practice of a naturopathic doctor when recommending herbs, minerals and other supplements according to tradi-

tions other than Oriental medicine traditions. In addition, § 18.15 (relating to practice responsibilities of acupuncturist and practitioner of Oriental medicine who is not a physician) is being amended to provide an exception to the prohibition on the use of the title "doctor" for an acupuncturist who is also registered as a naturopathic doctor.

The Board proposes to add Subchapter M to Chapter 18 to implement the provisions of the NDRA. Section 18.901 (relating to purpose) notes that this subchapter implements the registration of naturopathic doctors as required under the NDRA. Section 18.902 (relating to definitions) will define necessary terms used in Subchapter M, including "authorization to practice," "CNME—Council on Naturopathic Medical Education," "merchandise," "naturopathic doctor," "NABNE—North American Board of Naturopathic Examiners," "NDRA," "NPLEX—Naturopathic Physicians Licensing Examinations," and "regionally accredited or pre-accredited college or university." Next, the Board proposes to include the process and requirements to apply for a registration as a naturopathic doctor in § 18.903 (relating to application for naturopathic doctor registration), including the qualifications for registration as a naturopathic doctor as set forth in section 202 of the NDRA. The Board also proposes to include the requirement that an applicant for registration as a naturopathic doctor shall have completed at least 3 hours of approved education/training in child abuse recognition and reporting requirements, as required under 23 Pa.C.S. § 6383(b)(3)(i) (relating to education and training). The Board is currently pursuing a separate rulemaking (16A-4941) setting forth the requirements for approved courses in child abuse recognition and reporting and intends to add an appropriate cross-reference once that rulemaking is final.

The Board is proposing to include the requirements for the biennial renewal of the naturopathic doctor registration in § 18.904 (relating to biennial registration of naturopathic doctor) as required by section 203(b) of the NDRA. Section 203(b) of the NDRA provides for renewal ...in a manner and at such intervals as the board shall determine by regulation...." As such, the Board is proposing that all registrations of naturopathic doctors will expire on December 31st of each even-numbered year, to correspond with the expiration of all existing licenses issued by the Board. The Board proposes to set forth the manner of renewing in subsection (b), which sets forth the requirements for renewal as informed by the existing practice of the Board. The Board proposes to require, as a condition of biennial renewal, the completion of at least 2 hours of approved continuing education in child abuse recognition and reporting, as required under 23 Pa.C.S. § 6383(b)(3)(ii).

Similarly, the Board is proposing to provide for reactivation of inactive and expired registrations in § 18.905 (relating to inactive status; reactivation of inactive and expired registration). Again, the manner in which expired and inactive registrations are reactivated is informed by the Board's existing practices and includes payment of applicable fees and the completion of the required continuing education in child abuse recognition and reporting.

Proposed § 18.906 (relating to display of registration) would set forth the requirement that a naturopathic doctor prominently display the certificate of registration and evidence of biennial renewal in a publicly accessible location at the registrant's regular place of business and have evidence of current registration available for inspection when providing services at other locations.

In proposed § 18.907 (relating to acceptable titles and professional designations by registrants and non-registrants; prohibited titles) the Board clarifies the acceptable titles that may be used by registered naturopathic doctors, as well as non-registrants who may hold themselves out as naturopaths, traditional naturopaths and similar titles. Section 201 of the NDRA (63 P.S. § 272.201) provides that "[i]t shall be unlawful for an individual to use the title of "naturopathic doctor" or "doctor of naturopathic medicine" unless that person is registered as a naturopathic doctor with the board." Proposed § 18.907 makes it clear that a naturopathic doctor who uses the designation "Dr." shall further identify himself or herself as a "naturopathic doctor," "registered naturopathic doctor" or "doctor of naturopathic medicine" and may not use any term or designation that implies that the naturopathic doctor is authorized to practice medicine or any other health care profession, unless the naturopathic doctor also holds a current and active authorization to practice the other profession issued by the appropriate licensing authority of this Commonwealth.

Next, the Board proposes to address informed consent and required disclosures in § 18.908 (relating to informed consent and disclosure of financial interests). In this section, the Board would require that the informed consent include notice that the naturopathic doctor is not a physician. Further, in subsection (b), the Board proposes a requirement that a naturopathic doctor inform the patient if the naturopathic doctor will receive any financial incentive for referring a patient to a purveyor of merchandise or services, or for recommending any merchandise to a patient.

In § 18.909 (relating to naturopathic records) the Board proposes standards for the creation and retention of patient records and would authorize a naturopathic doctor to charge patients no more than the applicable costs for production of health records as annually adjusted by the Secretary of Health and published in the *Pennsylvania Bulletin*. It would further prohibit a naturopathic doctor from requiring payment for naturopathic services rendered as a condition of releasing records to a patient or the patient's designee.

Proposed § 18.910 (relating to advertising) sets forth information that must be included in all advertisements for naturopathic services, as well as standards for what may not be included in advertisements. Items that must be included in all advertisements include the name of the naturopathic doctor as registered with the Board and the words "naturopathic doctor" or "doctor of naturopathic medicine." Prohibitions include misrepresentations and other statements that are likely to mislead or deceive, those that create false or unjustified expectations as to results and those that imply that a manifestly incurable condition can be cured or that guarantee a cure of any condition. The Board is prohibiting statements recommending any modality or service that is inconsistent with the health, safety and welfare of the public. In addition, a registered naturopathic doctor may not include the term "physician" unless also licensed as a physician or physician assistant by the Board or the State Board of Osteopathic Medicine.

Proposed § 18.911 (relating to Code of Ethics) would establish the ethical principles for registered naturopathic doctors in this Commonwealth. This proposal was informed by the ethical standards of other health care professions regulated by the Board and the ethical standards for licensed naturopathic doctors in other states

and by National organizations such as the American Association of Naturopathic Physicians. These standards include items relating to competence, confidentiality and privacy, informed consent and maintenance of professional boundaries. Specific unethical conduct is prohibited such as making misrepresentations relating to credentials, qualifications or affiliations; engaging in fraudulent, dishonest or deceitful conduct; exploiting the professional relationship including a person, sexual, romantic or financial relationship; and engaging in sexual misconduct.

Proposed § 18.912 (relating to sexual misconduct) would make it clear that sexual misconduct, to include sexual exploitation of a current or former patient or of an immediate family member of a patient, and sexual behavior with a current patient, constitute unprofessional conduct and subjects the naturopathic doctor to disciplinary action.

Finally, proposed § 18.913 (relating to grounds for discipline) sets forth the grounds for discipline of a naturopathic doctor, including those reasons set forth in section 204 of the NDRA (63 P.S. § 272.204), and additional reasons such as engaging in fraud in obtaining a registration as a naturopathic doctor; false or deceptive advertising; aiding, assisting, employing or advising an unregistered individual to hold themselves out in a manner which states or implies that the individual is a naturopathic doctor; paying or receiving a commission, bonus, kickback or rebate or engaging in a fee splitting arrangement based on patient referrals; promoting the sale of services, drugs, devices, appliances or goods to a patient so as to exploit the patient for financial gain; offering to treat or cure a disease by a secret method; failing to maintain records; and failing to cooperate with a lawful investigation of the Board. Subsection (b) summarizes the panoply of potential disciplinary and corrective actions that the Board may impose for violations as authorized by the NDRA, $_{
m the}$ 63 Pa.C.S. § 3108(b) (relating to civil penalties), including denying an application for registration, administering a public reprimand, imposing probation or other restrictions on a registration, requiring other corrective actions or assessing monetary civil penalties and costs of investiga-

Fiscal Impact and Paperwork Requirements

The only fiscal impacts of this proposed rulemaking are the fees imposed upon naturopathic doctors for initial registration (\$100) or biennial renewal (\$50). Naturopathic doctors applying for initial registration, biennial renewal of registration or reactivation of an inactive or expired registration will be required to submit online applications and submit required documentation to the Board.

Sunset Date

The Board continuously monitors the effectiveness of its regulations. Therefore, no sunset date has been assigned. $Regulatory\ Review$

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on November 30, 2021, the Board submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House Professional Licensure Committee and the Senate Consumer Protection and Professional Licensure Committee. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey comments, recommendations or objections to

the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections shall specify the regulatory review criteria in section 5.2 of the Regulatory Review Act (71 P.S. § 745.5b) which have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Board, the General Assembly and the Governor.

Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding this proposed rulemaking to Shana Walter, Counsel, State Board of Medicine, P.O. Box 69523, Harrisburg, PA 17106-9523, or by e-mail to RA-STRegulatoryCounsel@pa.gov, within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Include in the subject line "16A-4953 (Registration of Naturopathic Doctors)" when submitting comments.

 $\begin{array}{c} \text{MARK B. WOODLAND, MS, MD,} \\ \text{Chairperson} \end{array}$

Fiscal Note: 16A-4953. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 16. STATE BOARD OF MEDICINE—GENERAL PROVISIONS

Subchapter A. BASIC DEFINITIONS AND INFORMATION

§ 16.1. Definitions.

The following words and terms, when used in this chapter and Chapters 17 and 18 (relating to State Board of Medicine—medical doctors; and State Board of Medicine—practitioners other than medical doctors), have the following meanings, unless the context clearly indicates otherwise:

Act—The Medical Practice Act of 1985 (63 P.S. \$\$ 422.1—[**422.45**] **422.53**).

Approved activity—A continuing medical education activity accepted for AMA PRA credit.

Board—The State Board of Medicine.

Board-regulated practitioner—A medical doctor, midwife, physician assistant, [drugless therapist,] athletic trainer, acupuncturist, practitioner of Oriental medicine, perfusionist, respiratory therapist, genetic counselor, prosthetist, orthotist, pedorthist, orthotic fitter, naturopathic doctor or an applicant for a license, registration or certificate that the Board may issue.

Subchapter B. GENERAL LICENSE, CERTIFICATION AND REGISTRATION PROVISIONS

§ 16.11. Licenses, certificates and registrations.

(1) Registration as a supervising physician of a physician assistant.

- (1.1) Initial registration as a naturopathic doctor.
- (2) Biennial registration of a license without restriction.
 - (3) Biennial registration of an extraterritorial license.
 - (4) Biennial registration of a midwife license.
- (5) Biennial registration of a physician assistant license.
- (6) [Biennial registration of a drugless therapist license] (Reserved).
- (7) Biennial registration of a limited license-permanent.

(18) Biennial registration of an orthotic fitter license.

(19) Biennial registration of a naturopathic doctor registration.

§ 16.12. General qualifications for licenses, registrations and certificates.

To qualify for [a] an initial license, registration or certificate issued by the Board, an applicant shall establish that the following criteria are satisfied:

* * * * * * * * * \$ 16.13. Licensure, certification, examination and registration fees.

* * * * *

(d) Acupuncturist licenses:

(1) Acupuncturist:

(2) Practitioner of Oriental medicine license:

 Application
 \$30

 Biennial renewal
 \$40

(e) [Drugless therapist license:

Biennial renewal......\$40] (Reserved).

* * * * *

(q) Orthotic Fitters:

Application for orthotic fitter temporary permit.... \$25

(r) Naturopathic doctor registration:

Application for initial registration\$100 Biennial renewal\$50

CHAPTER 18. STATE BOARD OF MEDICINE—PRACTITIONERS OTHER THAN MEDICAL DOCTORS

Subchapter B. REGISTRATION AND PRACTICE OF ACUPUNCTURISTS AND PRACTITIONERS OF ORIENTAL MEDICINE

§ 18.13a. Requirements for licensure as a practitioner of Oriental medicine.

(d) This subsection does not apply to a medical doctor licensed as an acupuncturist nor does it restrict the practice of medicine by a medical doctor.

- (e) This section does not limit the practice of a naturopathic doctor who is also licensed as an acupuncturist when recommending herbs, minerals and other supplements, or combinations, according to traditions other than Oriental medicine traditions.
- § 18.15. Practice responsibilities of acupuncturist and practitioner of Oriental medicine who is not a physician.

* * * * *

- (b) Identification of acupuncturist or practitioner of Oriental medicine. An acupuncturist who is not a medical doctor shall wear a tag or badge with lettering clearly visible to the patient bearing the acupuncturist's name and the title "acupuncturist" or "practitioner of Oriental medicine," as appropriate. The use of the [word doctor] words "doctor," "physician" or any title or abbreviation implying licensure as a physician on this tag or badge is prohibited; provided, however, that an individual licensed as an acupuncturist who also possesses a current and active registration as a naturopathic doctor may utilize the title "Doctor of Naturopathic Medicine," "Naturopathic Doctor" or the abbreviation "N.D." in addition to the title "acupuncturist".
- § 18.15a. Scope of practice of acupuncturists and practitioners of Oriental medicine.

* * * * *

- (c) This subsection does not limit the scope of practice of a medical doctor who is registered as an acupuncturist.
- (d) This section does not limit the scope of practice of a naturopathic doctor when recommending herbs minerals and other supplements, or combinations, according to traditions other than Oriental medicine traditions.

(*Editor's Note*: The following subchapter is proposed to be added and printed in regular type to enhance readability.)

Subchapter M. REGISTRATION OF NATUROPATHIC DOCTORS

18.901.	Purpose.
18.902.	Definitions.
18.903.	Application for naturopathic doctor registration.
18.904.	Biennial registration of naturopathic doctor.
18.905.	Inactive status; reactivation of inactive or expired registration
18.906.	Display of registration.
18.907.	Acceptable titles and professional designations by registrant
	and non-registrants; prohibited titles.
18.908.	Informed consent and disclosure of financial interests.
18.909.	Naturopathic records.
18.910.	Advertising.
18.911.	Code of Ethics.
18.912.	Sexual misconduct.

§ 18.901. Purpose.

Grounds for discipline.

Sec.

18.913.

This subchapter implements the Naturopathic Doctor Registration Act (63 P.S. §§ 272.101—272.301) pertaining to the registration of naturopathic doctors.

§ 18.902. Definitions.

The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise:

Authorization to practice—A license, registration, certificate, permit, authorization or approval issued by a Federal or state agency which authorizes the holder to

advertise, engage in, or both advertise and engage in the practice of a profession or occupation.

CNME—Council on Naturopathic Medical Education— The accrediting body which accredits schools of naturopathic medicine for the education of naturopathic doctors.

Merchandise—Items that can be sold including vitamins, supplements, food, food extracts, homeopathic remedies, botanical medicines, herbs and natural substances.

NABNE—North American Board of Naturopathic Examiners—The organization which administers the Naturopathic Physicians Licensing Examinations (NPLEX).

Naturopathic doctor—An individual who holds an active registration issued by the Board under the NDRA.

NDRA—The Naturopathic Doctor Registration Act (63 P.S. §§ 272.101—272.301).

NPLEX—Naturopathic Physicians Licensing Examinations—The licensing examination accepted by the Board as a prerequisite to registration, consisting of Part I—Biomedical Science Examination and Part II—Core Clinical Science Examination, or its successor recognized by the Board.

Regionally accredited or pre-accredited college or university—A college or university which is accredited or preaccredited by one of the following:

- (1) Accrediting Commission of Career Schools and Colleges.
- (2) Accrediting Council for Continuing Education and Training.
- (3) Accrediting Council for Independent Colleges and Schools.
 - (4) Council on Occupational Education.
 - (5) Distance Education Accrediting Commission.
 - (6) Higher Learning Commission.
 - (7) Middle States Commission on Higher Education.
 - (8) Middle States Commission on Secondary Schools.
 - (9) New England Commission of Higher Education.
- (10) New York State Board of Regents and the Commissioner of Education.
- (11) Northwest Commission on Colleges and Universities.
- (12) Southern Association of Colleges and Schools, Commission on Colleges.
- (13) Western Association of Schools and Colleges, Accrediting Commission for Community and Junior Colleges
- (14) Western Association of Schools and Colleges, Senior Colleges and University Commission.
- (15) Any other regional or national accrediting agency which has been recognized by the United States Department of Education as being a reliable authority concerning the quality of education or training offered by the institutions of higher education or higher education programs they accredit.

§ 18.903. Application for naturopathic doctor registration.

(a) An applicant for a registration to practice naturopathic medicine shall submit, on an application made available by the Board, a completed application for a registration, including the necessary supporting documents and pay the application fee in § 16.13 (relating to licensure, certification, examination and registration fees).

- (b) Except as otherwise provided by law, the Board will issue a registration to practice naturopathic medicine to an applicant who meets all of the following requirements:
- (1) Holds a bachelor's degree from a regionally accredited or pre-accredited college or university or the equivalent.
- (2) Holds a doctoral degree from a naturopathic school accredited by the CNME which consists of at least 4,100 total credit hours in basic and clinical sciences and naturopathic philosophy and modalities, including at least 2,500 hours of academic instruction and at least 1,200 hours of supervised clinical training. Proof of the degree shall be sent directly from the applicant's education program and include an official transcript.
- (3) Has passed Parts I and II of a competency-based National naturopathic licensing examination administered by the NABNE or a successor agency. An applicant who graduated prior to 1986 shall demonstrate a passing score on a state naturopathic examination.
- (4) Holds a current basic cardio-pulmonary resuscitation (CPR) certificate issued by the American Heart Association, American Red Cross or a similar health authority or professional body approved by the Board.
- (5) Has completed at least 3 hours of approved education/training in child abuse recognition and reporting requirements as set forth in 23 Pa.C.S. § 6383(b)(3)(i) (relating to education and training).
 - (6) Is of good moral character.
- (c) The Board may deny an application for registration as a naturopathic doctor upon any of the grounds for disciplinary action in § 18.913 (relating to disciplinary action for applicants and naturopathic doctors).

§ 18.904. Biennial registration of naturopathic doctor.

- (a) The registration of a naturopathic doctor will expire biennially on December 31 of each even-numbered year in accordance with § 16.15 (relating to biennial registration; inactive status and unregistered status). A naturopathic doctor may not use the title of "naturopathic doctor," "doctor of naturopathic medicine" or any other term implying that the individual is currently registered as a naturopathic doctor unless the individual holds a current and unexpired registration.
- (b) As a condition of biennial renewal, a naturopathic doctor shall:
- (1) Submit a completed application, including payment of the biennial registration fee in § 16.13 (relating to licensure, certification, examination and registration fees).
- (2) Disclose on the application any authorization to practice as a naturopathic doctor in another state, district, territory, possession or country.
- (3) Disclose on the application disciplinary action pending before, or taken by, the appropriate licensing, registration or certification authority in another jurisdiction since the most recent application for biennial registration, whether or not authorized to practice or advertise in that other jurisdiction.
- (4) Affirm that the applicant holds a current basic cardio-pulmonary resuscitation (CPR) certificate issued by

- the American Heart Association, American Red Cross or a similar health authority or professional body approved by the Board.
- (5) Certify that the applicant has completed at least 2 hours of approved continuing education in child abuse recognition and reporting as set forth in 23 Pa.C.S. § 6383(b)(3)(ii) (relating to education and training).

§ 18.905. Inactive status; reactivation of inactive or expired registration.

- (a) A naturopathic doctor may request in writing that the Board place the registration on inactive status. Confirmation of inactive status will be forwarded to the registrant. A naturopathic doctor may not use the title of "naturopathic doctor," "doctor of naturopathic medicine" or any other term implying that the individual is currently registered as a naturopathic doctor while on inactive status.
- (b) To reactivate an inactive or expired registration, the registrant shall apply for reactivation by completing an application for reactivation on a form made available by the Board. The registrant shall:
- (1) Pay the current biennial registration fee specified in § 16.13 (relating to licensure, certification, examination and registration fees) and any applicable late fees required under section 225 of the Bureau of Professional and Occupational Affairs Fee Act (63 P.S. § 1401-225).
- (2) Disclose whether the registrant used the title of "naturopathic doctor," "doctor of naturopathic medicine" or any other term implying that the individual was currently registered as a naturopathic doctor in this Commonwealth while the registration was inactive or expired.
- (3) Disclose on the application any authorization to practice as a naturopathic doctor in another state, district, territory, possession or country.
- (4) Disclose on the application disciplinary action pending before or taken by the appropriate licensing, registration or certification authority in another jurisdiction since the most recent application for biennial registration, whether or not authorized to practice or advertise in that other jurisdiction.
- (5) Submit evidence the registrant holds a current basic cardio-pulmonary resuscitation (CPR) certificate issued by the American Heart Association, American Red Cross or a similar health authority or professional body approved by the Board.
- (6) Verify completion of at least 2 hours of approved continuing education in child abuse recognition and reporting in the 2 years immediately preceding the application for reactivation as set forth in 23 Pa.C.S. § 6383(b)(3)(ii) (relating to education and training).
- (c) A registrant who has not had clinical contact with patients for 4 years or more shall demonstrate current competency and qualification to hold forth as a naturopathic doctor by demonstrating a passing score on the NPLEX examination, completed within 12 months of the application to reactivate the registration.
- (d) Payment of applicable late fees required under section 225 of the Bureau of Professional and Occupational Affairs Fee Act (63 P.S. § 1401-225) does not preclude the Board from taking disciplinary action for utilizing the title of "naturopathic doctor," "doctor of naturopathic medicine" or any other term implying that the individual was currently registered as a naturopathic doctor while holding an inactive or expired registration.

§ 18.906. Display of registration.

A naturopathic doctor registrant shall prominently display the certificate of registration and evidence of biennial renewal in a publicly accessible location at the registrant's regular place of business. The registrant shall have evidence of current registration available for inspection by authorized agents of the Board and by persons receiving services when the naturopathic doctor provides services at locations other than the registrant's regular place of business.

§ 18.907. Acceptable titles and professional designations by registrants and non-registrants; prohibited titles.

- (a) An individual must have a current, active and unsuspended registration to claim to be, or hold oneself out as, a naturopathic doctor, registered naturopathic doctor, doctor of naturopathic medicine or use any similar title implying that the individual holds a current registration as a naturopathic doctor in this Commonwealth.
- (b) An individual who has not registered with the Board may claim to be, and hold oneself out as, a naturopath or a traditional naturopath and use any similar title implying that the individual practices naturopathy so long as the title does not also imply that the individual is a naturopathic doctor registered with the Board
- (c) A naturopathic doctor who uses the designation "Dr." shall further identify himself or herself as a "naturopathic doctor," "registered naturopathic doctor" or "doctor of naturopathic medicine" and may not use any term or designation that would imply that the naturopathic doctor is licensed or authorized to practice medicine and surgery, dentistry, podiatry, optometry, psychology, nursing, physical therapy, acupuncture, chiropractic, genetic counseling, athletic training, massage therapy or any other health care profession, unless that individual also holds a current and active authorization to practice the other profession issued by the appropriate licensing authority of this Commonwealth.

§ 18.908. Informed consent and disclosure of financial interests.

- (a) A naturopathic doctor shall obtain written informed consent from the patient prior to providing naturopathic services to the patient. The informed consent shall include notification to the patient that the naturopathic doctor is not a physician. This subsection shall not apply to registrants who are also currently and actively licensed to practice as a physician in this Commonwealth.
- (b) A naturopathic doctor shall disclose to patients and prospective patients if the naturopathic doctor receives any commission, rebate, referral fee or similar financial incentive in connection with the referral of a patient to purveyors of merchandise or services, or for recommending any merchandise to a patient.

§ 18.909. Naturopathic records.

- (a) A naturopathic doctor shall maintain patient records that accurately describe the patient's concerns, evidence the naturopathic doctor's plan of service and implementation of service and document the patient's response to any services provided.
- (b) All patient records for minors and adults shall be retained for a minimum period of 7 years from the date of the service for which a naturopathic record entry is required. Patient records for minor patients shall also be

- retained until 1 year after the minor patient reaches majority, even if this means that the naturopathic doctor retains the record for a period of more than 7 years.
- (c) Upon written request, a naturopathic doctor shall make true, correct and legible copies of the written records of service available to the patient or the person or persons designated by the patient.
- (d) Payment for naturopathic services rendered may not be required as a condition to making the written records of service available to the patient or the patient's designee. A naturopathic doctor may require pre-payment of the costs to copy and produce the naturopathic records. The maximum applicable copying and reproduction costs for naturopathic service records shall be the same as those costs applicable to production of health records as annually adjusted by the Secretary of the Department of Health and published in the *Pennsylvania Bulletin*.

§ 18.910. Advertising.

- (a) Any advertisement by a naturopathic doctor shall contain both of the following:
- (1) The name of the naturopathic doctor as registered with the Board.
- (2) The words "naturopathic doctor" or "doctor of naturopathic medicine."
- (b) Advertisements by a naturopathic doctor may not contain any of the following:
- (1) The word "physician" unless the naturopathic doctor is also currently and actively licensed as a physician or physician assistant in this Commonwealth.
- (2) Any words or phrases indicating or implying that the naturopathic doctor is "board certified" or "board eligible" unless the certification body is also disclosed.
 - (3) Statements containing misrepresentations of facts.
- (4) Statements that cannot be verified by the Board for truthfulness.
- (5) Statements likely to mislead or deceive because of their context or because the statements make only a partial disclosure of relevant facts.
- (6) Statements intended to, or likely to, create false or unjustified expectations of favorable results.
- (7) Statements containing representations or implications that can reasonably be expected to cause an ordinary prudent person to misunderstand or be deceived.
- (8) Statements that are untruthful and improbable or contain misstatements, falsehoods, misrepresentations, distorted or fabulous statements as to cures.
- (9) Statements that misrepresent the nature, characteristics or qualities of natural substances or services provided by a naturopathic doctor.
- (10) Statements that a manifestly incurable condition can be cured or that guarantee a cure of any condition.
- (11) Statements promoting herbal, natural or dietary supplements as drugs.
- (12) Statements recommending any modality of service that is inconsistent with the health, safety and welfare of the public.

§ 18.911. Code of Ethics.

(a) Naturopathic doctors shall concern themselves primarily with the welfare of the patient.

- (b) A naturopathic doctor who suffers from a physical, mental or emotional impairment, including substance abuse, that impacts the individual's ability to practice naturopathic medicine shall seek professional treatment and refrain from the practice of naturopathic medicine until the impairment no longer exists or reasonable accommodations can be made.
 - (c) A naturopathic doctor shall:
- (1) Respect and maintain the privacy and confidentiality of the patient.
- (2) Disclose the patient's records or information about the patient only with the patient's consent or as required by law.
- (3) Adequately safeguard confidential patient information, including storage and disposal of records.
- (4) Provide sufficient information to a patient to allow the patient to make an informed decision regarding care, including:
- (i) The purpose and nature of a naturopathic evaluation or service regimen.
 - (ii) Alternatives to naturopathic care.
- (iii) Side effects and benefits of a proposed service regimen.
 - (iv) The estimated cost of services.
 - (v) The right of the patient to withdraw from services.
- (5) Maintain professional boundaries, even when the patient initiates crossing the boundaries of the professional relationship.
- (6) Decline to administer service if the naturopathic doctor believes that a service is contraindicated or unjustified.
- (7) Make referrals only to registered naturopathic doctors or other qualified and duly licensed health care providers.
- (8) Accurately inform the patient, other health care professionals and the public of the limitations of the practice of naturopathic medicine.
- (9) Adequately assess the patient to determine if contraindications against naturopathic service exist and refer the patient to an appropriate health care practitioner.
- (10) At all times respect the patient's dignity, autonomy and privacy.
- (11) Cooperate with any lawful investigation conducted by the Board, including all of the following:
- (i) Furnishing information requested in a timely manner as directed by the Board.
 - (ii) Complying with a subpoena.
- (iii) Responding to a complaint at the request of the Board.
- (iv) Providing meaningful and timely access to relevant patient records.
- (12) Report to the Board misconduct in the practice of naturopathic medicine.
 - (d) A naturopathic doctor may not:
- (1) Misrepresent credentials, qualifications or affiliations, and shall attempt to correct others who misrepresent the naturopathic doctor's credentials, qualifications or affiliations.

- (2) Knowingly engage in or condone behavior that is fraudulent, dishonest or deceitful.
- (3) Engage in a commercial activity which conflicts with the duties of a naturopathic doctor.
- (4) Perform naturopathic medicine on a patient if a contraindication against naturopathic service exists.
- (5) Intimidate, threaten, influence or attempt to influence any person regarding any violation of law or regulation.
- (6) Aid or abet any individual violating or attempting to violate any provision of law or regulation.
- (7) Accept a patient for service, or continue unnecessary service, when the patient cannot be reasonably expected to benefit from the service.
- (8) Receive remuneration from, or provide remuneration to, or split a fee, for either making or accepting a referral of the patient to or from another health care provider.
- (9) Make a guarantee or promise about the efficacy of a particular course of care, the naturopathic doctor's practice or the anticipated results of care.
- (10) Exploit the professional relationship by either of the following:
 - (i) Continuing service unnecessarily.
- (ii) Charging for a service not provided or different from what was actually provided.
- (11) Exploit a relationship with a patient, staff member or student for the naturopathic doctor's personal advantage including, but not limited to, a personal, sexual, romantic or financial relationship.
 - (12) Engage in sexual misconduct.
- (e) A naturopathic doctor may not perform a service or provide a service that the naturopathic doctor is not qualified to perform, or which is beyond the scope of the naturopathic doctor's education, training, capabilities or experience.
- (f) A naturopathic doctor may not construe any failure to specify a particular ethical, legal or professional duty in this subchapter as a denial of the existence of other ethical, legal or professional duties or responsibilities that are equally as important and generally recognized in the naturopathic medicine profession.

§ 18.912. Sexual misconduct.

- (a) Sexual exploitation by a naturopathic doctor of a current or former patient, or of an immediate family member of a patient, constitutes unprofessional conduct, is prohibited and subjects the naturopathic doctor to disciplinary action under section 204(8) of the NDRA (63 P.S. § 272.204(8)).
- (b) Sexual behavior that occurs with a current patient, other than the naturopathic doctor's spouse, constitutes unprofessional conduct, is prohibited and subjects the practitioner to disciplinary action under section 204(8) of the NDRA.
- (c) When a naturopathic doctor was involved with the management or directly provided naturopathic services to a patient other than the naturopathic doctor's spouse for a mental health disorder, any sexual behavior with that patient which occurs prior to the 2-year anniversary of the termination of the professional relationship consti-

tutes unprofessional conduct, is prohibited and subjects the naturopathic doctor to disciplinary action under section 204(8) of the NDRA.

- (d) A practitioner who engages in conduct prohibited by this section will not be eligible for placement into an impaired professional program in lieu of disciplinary or corrective actions.
- (e) Consent is not a defense to conduct prohibited by this section.

§ 18.913. Grounds for discipline.

- (a) The Board shall have the authority to impose disciplinary or corrective measures on a naturopathic doctor or applicant for registration as a naturopathic doctor for the reasons set forth in section 204 of the NDRA (63 P.S. § 272.204) and any of the following:
- (1) Fraudulently or deceptively obtaining, or attempting to obtain, or using a registration or assisting another in fraudulently or deceptively obtaining or using a registration.
 - (2) Using false, deceptive or misleading advertising.
- (3) Advertising, practicing or attempting to practice under a name other than the naturopathic doctor's name as registered with the Board; provided, however, that a naturopathic doctor may advertise utilizing a business name if the advertisement also includes the naturopathic doctor's name as registered by the Board.
- (4) Aiding, assisting, employing or advising any unregistered individual to hold himself or herself out in a manner which states or implies the unregistered individual is a naturopathic doctor.
- (5) Paying or receiving any commission, bonus, kick-back or rebate, or engaging in any split-fee arrangement in any form with a licensed physician, organization, agency or other person, either directly or indirectly, for patients referred to other health care providers.
- (6) Promoting the sale of services, drugs, devices, appliances or goods to a patient so as to exploit the patient for financial gain.
- (7) Failing to keep written records justifying the course of service of a patient.

- (8) Offering, undertaking or agreeing to cure or treat a disease by a secret method, treatment, product or medicine.
- (9) Failing to cooperate with a lawful investigation of the Board.
- (b) When the Board is empowered to take disciplinary or corrective action under the provisions of the NDRA, the Board's regulations or other statutory or regulatory authority, the Board may impose one or more of the following disciplinary or corrective actions as set forth in section 206 of the NDRA (63 P.S. § 272.206), section 42 of the act (63 P.S. § 422.42) and 63 Pa.C.S. § 3108 (relating to civil penalties):
 - (1) Deny the application for registration.
- (2) Administer a public reprimand with or without probation.
- (3) Revoke, suspend, limit or otherwise restrict a registration.
- (4) Require the registrant to submit to the care, counseling or treatment of a physician or a psychologist designated by the Board.
- (5) Require the registrant to take refresher educational courses or demonstrate passage of the NPLEX examination, or both.
- (6) Stay enforcement of any suspension and place the registrant on probation with the right to vacate the probationary order for noncompliance.
- (7) Impose a civil penalty of up to \$1,000 in accordance with the NDRA.
- (8) Impose a civil penalty of up to \$10,000 in accordance with 63 Pa.C.S. \S 3108(b); provided, however, that the Board will not impose a civil penalty under the NDRA and also impose a civil penalty under 63 Pa.C.S. \S 3108(b) for the same violation, as prohibited by 63 Pa.C.S. \S 3108(c)(2).
- (9) Impose the costs of investigation underlying the disciplinary action.

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