

**BOARD OF PODIATRIC MEDICAL EXAMINERS
OPEN SESSION MEETING VIA GOOGLE MEETS**

AGENDA

February 08, 2024_

Location: Google Meet meet.google.com/axh-kefj-vfo

Join by phone: (US) +1 724-542-5434 PIN: 878958198

A. ORDER OF BUSINESS

- 1. Call to Order- Roll Call**
- 2. COMAR 10.01.14.02.B: Except in instances when a public body expressly invites public testimony, questions, comments, or other forms of public participation, or when public participation is otherwise authorized by law, a member of the public attending an open session may not participate in the session.**
- 3. Approval of minutes from January 11, 2024, meeting** **Tab A**

B. BOARD PRESIDENT'S REPORT

C. EXECUTIVE DIRECTOR'S REPORT

D. OLD BUSINESS:

- 1. Update Discussion on Amending the Language for the Civil Settlement Reporting Requirements Application Question**

Update from Board staff on the amendment of the licensing/renewal application.
- 2. Update Licensing Statistics for the 2024-2025 Renewal**

Rectification of the number of renewed licensees, from the 1/11/2024 meeting
- 3. Ratifying the Executive Meeting Minutes concerning CME Credits awarded for MPMA and MBPME meetings.**
- 4. Letter of Opposition (Board of Physicians and various Boards)-SB 54** **Tab B**

SB 54-Occupational Licensing and Certification – Criminal History – Prohibited Disclosures and Predetermination Review Process

E. NEW BUSINESS:

1. Discussion Concerning Completion of Character and Fitness Questions on The Renewal Application

2. HB 642 - Apprenticeships in Licensed Occupations Act of 2024

Tab C

Requiring professional and occupational regulatory boards to issue licenses, certifications, and registrations to individuals who complete an apprenticeship program that is established under the Maryland Apprenticeships in Licensed Occupations Act

3. HB 581 State Government - Permits, Licenses, and Certificates - Processing (Transparent Government Act of 2024)

Purpose: Requiring certain departments and independent units to create a certain catalog of information relating to permits, licenses, and certificates issued by the department or independent unit and submit the catalog to the Governor on or before September 1, 2024; requiring certain departments and independent units to post certain information relating to permits, licenses, and certificates on the website of the department or independent unit on or before December 1, 2024; establishing the Government Efficiency Commission; etc.

4. Topics Newsletter- Winter 2023

Tab D

F. ADJOURNMENT



BOARD OF PODIATRIC MEDICAL EXAMINERS

OPEN SESSION MEETING VIA GOOGLE MEET

PUBLIC MEETING MINUTES

January 11, 2024

Location: Google Meet meet.google.com/jwi-wwbu-wkg

Join by phone: (US) +1 573-721-9216 PIN: 998843847

The Public Meeting commenced at 1:06pm, opened by the Board President, Dr. Aparna Duggirala.

Roll call was initiated by the President.

Board members present: Drs. Yvonne Umezurike, H. David Gottlieb, Bruce Fox, and Adam Silverman.

Consumer Members Present: Ms. Frona Kroopnick. Ms. Lynne Brecker, R.N.

Board staff present: Eva Schwartz, Executive Director, Elizabeth Kohlhepp, Deputy Executive Director, and Kiana Nicholson, Licensing Coordinator.

Office of the Attorney General: Kristen Fon Lim, AAG, Board Counsel.

Guests: Richard Bloch, Esq., Executive Director and Chief Counsel, representing MPMA. Dr Jay LeBow, Director Emeritus, representing FPMB. Zakiyah Holmes- MDH. Lillian Resse-MDH.

Dr. Aparna Duggirala cited COMAR 10.01.14.02.B: "Except in instances when a public body expressly invites public testimony, questions, comments, or other forms of public participation, or when public participation is otherwise authorized by law, a member of the public attending an open session may not participate in the session."

A. MINUTES

1. Approval of minutes from the November 09, 2023, meeting.

The meeting minutes from the November 09, 2023, public meeting, were approved unanimously, as submitted.

B. BOARD PRESIDENT'S REPORT

Dr. Duggirala did not report at this time.

C. EXECUTIVE DIRECTOR'S REPORT

Ms. Schwartz shared that there are several bills for the Board's vote today that will be discussed later during the public session. Ms. Schwartz reported on a recent article from National Practitioner Data Bank that shared resources and reporting instructions for addiction related self-referrals. The article specified that if a practitioner voluntarily enters a rehabilitation facility and is NOT suspended by a Board, then it does not need to be reported to the NPDB. Information should be reported to the Board in instances where the **license or clinical privileges were suspended**, and the practitioner was required to enroll in a voluntary rehabilitation program.

D. OLD BUSINESS:

1. Update Discussion on Amending the Language for the Civil Settlement Reporting Requirements Application Question

Ms. Lim shared that the Board voted to approve the amended language during the November 9, 2023, meeting. The amended language was provided to Board staff and all applications will be updated immediately.

E. NEW BUSINESS:

1. Discussion Concerning Completion of Character and Fitness Questions on the License Renewal Application

The discussion concerning completion of character and fitness questions on the license renewal application was rectified in the discussion on amending the language for the civil settlement reporting requirements application question under Old Business.

2. FPMB - [Allied Organization Announcement #1] Council on Podiatric Medical Education - Updated Frequently Asked Questions

Ms. Schwarz shared that the FPMB- [Allied Organization Announcement #1] Council on Podiatric Medical Education- Updated Frequently Asked Questions was provided for informational purposes.

3. Regulatory Legislative Responsibilities

The Board was given a copy of a document written by Ms. Lillian Reese explaining what the Regulatory Legislative Responsibilities are for a Legislative Session. Dr. Duggirala shared that the Regulatory Legislative Responsibilities information sheet was very informative and well written. Ms. Schwartz thanked Ms. Lillian Reese for putting the information together and shared that the Board members are very appreciative. Additionally, Ms. Schwartz asked the Board to follow the proposed legislation this session and if there is a bill relevant to Podiatry or of high importance, that at least one

Board member volunteer to testify in Annapolis. Ms. Schwartz emphasized the importance for members of the profession to testify in person on relevant matters.

4. SB 3 - Health Occupations - Service Members, Veterans, and Military Spouses - Temporary Licensure, Certification, Registration, and Permitting

The Board reviewed SB 3- Health Occupations- Service Members, Veterans, and Military Spouses- Temporary Licensure, Certification, Registration, and Permitting. Ms. Resse shared that there are currently five (5) Boards that wrote letters of information in response to the proposed Bill.

Dr. Duggirala inquired how this Bill would impact Board operations, especially regarding proof of Board scores and Residency completion. The statements in subsection 2(1), “ (d) (24)If a health occupations board determines that a service member, veteran, or; (25)military spouse does not meet the education, training, or experience requirements for; (26)licensure, certification, or registration, a representative of the board shall assist the service; (27) member, veteran, or military spouse in identifying: 28 (1) Programs that offer relevant education or training; or 29 (2) Ways of obtaining needed experience”, would not meet compliance with the Board’s licensing requirements, whether a temporary, full, or limited license is issued efficiently. The Board is currently in compliance with the proposed Bill and currently accomplishing the Legislation’s proposed goals. After discussion, the Board voted unanimously to take “No Position” on the Bill.

5. SB 54 (HB 175) - Occupational Licensing and Certification - Criminal History - Prohibited Disclosures and Predetermination Review Process

The Board was provided a synopsis of SB 54 (HB 175) - Occupational Licensing and Certification - Criminal History - Prohibited Disclosures and Predetermination Review Process for review. Ms. Schwartz shared that the proposed Legislation would prohibit the Board from being able to deny an applicant based on their Criminal History Records Check and limit the offenses that need to be disclosed to the Board for licensing purposes. Dr. Fox questioned how the proposed Legislation will affect employers asking employees about criminal history prior to hiring. Ms. Lim stated that while criminal history reporting authorization is illegal in private employment; CJIS is Federal law and each Boards regulations have blanket language covering the criminal history requirement. Additionally, Ms. Lim emphasized criminal history checks are permissible during the licensing process due to government oversight. After discussion, the Board voted unanimously to write a “Letter of Concern”.

6. SB 221 (HB 146) - Health Occupations Boards - Reciprocal Licensure and Certification

The Board provided a copy of SB 221 (HB 146)- Health Occupations Boards- Reciprocal Licensure and Certification for review. Ms. Schwartz shared that the proposed Bill provides reciprocity to applicants, however reciprocity is not in the Board's current Statute or COMAR. Ms. Reese emphasized that the Bill permits reciprocity within the State; however, the relevant Boards ultimately decide whether a license may be granted. After discussion, the Board voted unanimously for "No Position" on the Bill.

7. New License Approval

a. Byun Sun, DPM

The above identified licensure candidate was approved unanimously for the issuance of a full Maryland license.

b. Cassandre Charles, DPM

The above identified licensure candidate was approved unanimously for the issuance of a full Maryland license.

F. ADJOURNMENT

With no further business, the Public Session of the Board meeting concluded at 1:58 PM.

Respectfully submitted by Eva Schwartz, Executive Director, Signature and date__

and Elizabeth Kohlhepp, Deputy Executive Director, Signature and date__

Signature by Frona Kroopnick, Board Secretary/Treasurer:__



Board of Physicians

Wes Moore, Governor · Aruna Miller, Lt. Governor · Harbhajan Ajrawat, M.D., Chair

2024 SESSION POSITION PAPER

BILL NO.: SB 54 – Occupational Licensing and Certification – Criminal History – Prohibited Disclosures and Predetermination Review Process
COMMITTEE: Finance / Education, Energy, and the Environment
POSITION: Letter of Opposition

TITLE: Occupational Licensing and Certification – Criminal History – Prohibited Disclosures and Predetermination Review Process

POSITION & RATIONALE:

The Maryland Board of Physicians, State Board of Dental Examiners, State Board of Pharmacy, State Acupuncture Board, State Board of Chiropractic Examiners, State Board of Massage Therapy Examiners, State Board of Morticians and Funeral Directors, State Board of Examiners in Optometry, State Board of Occupational Therapy Practice, State Board of Podiatric Medical Examiners, State Board of Professional Counselors and Therapists, State Board of Examiners of Psychologists, and State Board of Social Work Examiners (the Boards) are respectfully submitting this letter of opposition for Senate Bill 54 – Occupational Licensing and Certification – Criminal History – Prohibited Disclosures and Predetermination Review Process (SB 54). While the intent of SB 54 is positive, the Boards are concerned that in practice, SB 54 would limit the ability of the Boards to thoroughly verify that applicants meet all licensure standards and could potentially place even more burdens on applicants with criminal convictions.

Under current law, applicants must submit a criminal history record check (CHRC) and/or disclose information regarding criminal history to obtain a health occupations license issued by the Boards. The Boards thoroughly review each applicant's criminal history and use the balancing factors outlined in Criminal Procedures Article §1-209, Maryland Annotated Code, when making determinations about licensure. It is exceedingly rare that the Boards deny an application based solely on the grounds of a criminal conviction. For example, in fiscal year 2023, the Maryland Board of Physicians processed 7,100 CHRCs, including 118 with positive results, but did not deny a single application due to criminal history.

While denial of licensure is rare, properly investigating prior criminal history is essential to the Boards' mission of safeguarding the public through the licensure of its health professionals. SB 54 would remove the requirement that applicants disclose certain criminal history, particularly for non-violent offenses and crimes that did not result in imprisonment. However, many offenses that would fall under this umbrella must by necessity still be treated extremely seriously by the Boards when licensing physicians, pharmacists, dentists, and other health care practitioners. For example, crimes of fraudulent conduct or non-violent crimes involving inappropriate sexual contact typically require a thorough investigation even when they do not result in terms of imprisonment. As healthcare providers have a particular place of trust within their communities and frequently deal with the most vulnerable members of the public, these investigations are necessary parts of the licensure process. Removing the disclosure requirements would hamper the ability of the Boards to fully investigate before issuing a license.

Furthermore, creating a predetermination review process for criminal convictions, while well intended, could have a deleterious effect on applicants. As referenced earlier, denials of licensure for reasons of criminal conviction are exceedingly rare and only occur after a thorough investigation and review of the context and circumstances surrounding the conviction. However, absent the full context and circumstances surrounding the conviction, in the interest of public safety, the Boards may be forced to err on the side of rejecting applications due to convictions that could potentially result in a denial of licensure but that might otherwise have been approved. The Boards would then need to establish an appeals process, which could be costly both for the Boards and the applicants and could potentially discourage applicants from ever submitting a full application following an initial rejection.

A predetermination process would also fail to encompass scenarios where a board approves issuing a license with conditions. For example, if a physician's criminal history seems to indicate a history of drug or alcohol abuse, the Maryland Board of Physicians may choose to issue the license but require, as a condition of licensure, that the applicant participate in the Maryland Physician Rehabilitation Program for monitoring and counseling. Scenarios such as these are far more common than outright denials of licensure but would not be possible as part of the predetermination review outlined in SB 54.

The Boards strongly believe that the application process should never place undue burdens on the applicant and have developed procedures to allow applicants with prior criminal convictions to be treated fairly, respectfully, and without unnecessary delays. Given the rarity of cases where a license was denied due to a previous criminal conviction, the Boards believe that these procedures have been demonstrably effective in ensuring that a criminal conviction is not a barrier to licensure. However, SB 54 would restrict the Boards' ability to properly protect the public. Therefore, the Boards would urge the Committee to submit an unfavorable report unless SB 54 is amended to remove the health occupations boards.

Thank you for your consideration. For more information, please contact:

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The opinion of the Boards expressed in this document does not necessarily reflect that of the Maryland Department of Health or the Administration.



HOUSE BILL 642

C3, C2, J2

EMERGENCY BILL

4lr3280
CF 4lr0691

By: **Delegate Harrison**

Introduced and read first time: January 25, 2024

Assigned to: Economic Matters

A BILL ENTITLED

1 AN ACT concerning

2 **Apprenticeships in Licensed Occupations Act of 2024**

3 FOR the purpose of requiring professional and occupational regulatory boards to issue
4 licenses, certifications, and registrations to individuals who complete an
5 apprenticeship program that is established under certain provisions of this Act, pass
6 a certain examination, and pay a certain fee; authorizing the Maryland Department
7 of Labor to develop a standard apprenticeship program for a licensed occupation or
8 profession; requiring the Department to establish a workgroup to establish
9 group-sponsored apprenticeships in each occupation or profession for which a
10 standard apprenticeship program is established; and generally relating to
11 occupational and professional apprenticeships.

12 BY adding to
13 Article – Agriculture
14 Section 1–202
15 Annotated Code of Maryland
16 (2016 Replacement Volume and 2023 Supplement)

17 BY adding to
18 Article – Business Occupations and Professions
19 Section 1–209
20 Annotated Code of Maryland
21 (2018 Replacement Volume and 2023 Supplement)

22 BY adding to
23 Article – Business Regulation
24 Section 1–211
25 Annotated Code of Maryland
26 (2015 Replacement Volume and 2023 Supplement)

27 BY adding to

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



Article – Environment

Section 1–206

Annotated Code of Maryland

(2013 Replacement Volume and 2023 Supplement)

BY adding to

Article – Health Occupations

Section 1–229

Annotated Code of Maryland

(2021 Replacement Volume and 2023 Supplement)

BY adding to

Article – Labor and Employment

Section 11–1601 through 11–1605 to be under the new subtitle “Subtitle 16.

Maryland Apprenticeships in Licensed Occupations Act”

Annotated Code of Maryland

(2016 Replacement Volume and 2023 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,

That the Laws of Maryland read as follows:

Article – Agriculture

1–202.

NOTWITHSTANDING THE QUALIFICATIONS REQUIRED FOR OCCUPATIONAL OR PROFESSIONAL LICENSURE, CERTIFICATION, OR REGISTRATION UNDER THIS ARTICLE, THE ISSUING AUTHORITY SHALL ISSUE A LICENSE, CERTIFICATION, OR REGISTRATION TO AN INDIVIDUAL WHO:

(1) COMPLETES AN APPRENTICESHIP PROGRAM THAT IS ESTABLISHED UNDER THE MARYLAND APPRENTICESHIPS IN LICENSED OCCUPATIONS ACT FOR THE APPLICABLE OCCUPATION OR PROFESSION;

(2) PASSES AN EXAMINATION REQUIRED BY THE ISSUING AUTHORITY; AND

(3) PAYS THE APPLICABLE LICENSING, CERTIFICATION, OR REGISTRATION FEE.

Article – Business Occupations and Professions

1–209.

NOTWITHSTANDING THE QUALIFICATIONS REQUIRED FOR OCCUPATIONAL OR

PROFESSIONAL LICENSURE, CERTIFICATION, OR REGISTRATION UNDER THIS ARTICLE, THE ISSUING AUTHORITY SHALL ISSUE A LICENSE, CERTIFICATION, OR REGISTRATION TO AN INDIVIDUAL WHO:

(1) COMPLETES AN APPRENTICESHIP PROGRAM THAT IS ESTABLISHED UNDER THE MARYLAND APPRENTICESHIPS IN LICENSED OCCUPATIONS ACT FOR THE APPLICABLE OCCUPATION OR PROFESSION;

(2) PASSES AN EXAMINATION REQUIRED BY THE ISSUING AUTHORITY;
AND

(3) PAYS THE APPLICABLE LICENSING, CERTIFICATION, OR REGISTRATION FEE.

Article – Business Regulation

1–211.

NOTWITHSTANDING THE QUALIFICATIONS REQUIRED FOR OCCUPATIONAL OR PROFESSIONAL LICENSURE, CERTIFICATION, OR REGISTRATION UNDER THIS ARTICLE, THE ISSUING AUTHORITY SHALL ISSUE A LICENSE, CERTIFICATION, OR REGISTRATION TO AN INDIVIDUAL WHO:

(1) COMPLETES AN APPRENTICESHIP PROGRAM THAT IS ESTABLISHED UNDER THE MARYLAND APPRENTICESHIPS IN LICENSED OCCUPATIONS ACT FOR THE APPLICABLE OCCUPATION OR PROFESSION;

(2) PASSES AN EXAMINATION REQUIRED BY THE ISSUING AUTHORITY;
AND

(3) PAYS THE APPLICABLE LICENSING, CERTIFICATION, OR REGISTRATION FEE.

Article – Environment

1–206.

NOTWITHSTANDING THE QUALIFICATIONS REQUIRED FOR OCCUPATIONAL OR PROFESSIONAL LICENSURE, CERTIFICATION, OR REGISTRATION UNDER THIS ARTICLE, THE ISSUING AUTHORITY SHALL ISSUE A LICENSE, CERTIFICATION, OR REGISTRATION TO AN INDIVIDUAL WHO:

(1) COMPLETES AN APPRENTICESHIP PROGRAM THAT IS ESTABLISHED UNDER THE MARYLAND APPRENTICESHIPS IN LICENSED

1 **OCCUPATIONS ACT FOR THE APPLICABLE OCCUPATION OR PROFESSION;**

2 **(2) PASSES AN EXAMINATION REQUIRED BY THE ISSUING**
3 **AUTHORITY; AND**

4 **(3) PAYS THE APPLICABLE LICENSING, CERTIFICATION, OR**
5 **REGISTRATION FEE.**

6 **Article – Health Occupations**

7 **1–229.**

8 **(A) IN THIS SECTION, “HEALTH OCCUPATIONS BOARD” MEANS A BOARD**
9 **AUTHORIZED TO ISSUE A LICENSE, CERTIFICATION, OR REGISTRATION UNDER THIS**
10 **ARTICLE.**

11 **(B) NOTWITHSTANDING THE QUALIFICATIONS REQUIRED FOR LICENSURE,**
12 **CERTIFICATION, OR REGISTRATION UNDER THIS ARTICLE, A HEALTH OCCUPATIONS**
13 **BOARD SHALL ISSUE A LICENSE, CERTIFICATION, OR REGISTRATION TO AN**
14 **INDIVIDUAL WHO:**

15 **(1) COMPLETES AN APPRENTICESHIP PROGRAM THAT IS**
16 **ESTABLISHED UNDER THE MARYLAND APPRENTICESHIPS IN LICENSED**
17 **OCCUPATIONS ACT FOR THE APPLICABLE HEALTH OCCUPATION;**

18 **(2) PASSES AN EXAMINATION REQUIRED BY THE HEALTH**
19 **OCCUPATIONS BOARD; AND**

20 **(3) PAYS THE APPLICABLE LICENSING, CERTIFICATION, OR**
21 **REGISTRATION FEE.**

22 **Article – Labor and Employment**

23 **SUBTITLE 16. MARYLAND APPRENTICESHIPS IN LICENSED OCCUPATIONS ACT.**

24 **11–1601.**

25 **(A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS**
26 **INDICATED.**

27 **(B) “APPRENTICESHIP” MEANS AN APPRENTICESHIP PROGRAM THAT**
28 **MEETS THE FEDERAL GUIDELINES AS SET FORTH IN 29 C.F.R. PART 29.**

29 **(C) “BOARD” MEANS A BOARD OR COMMISSION IN THE DEPARTMENT, THE**

1 MARYLAND DEPARTMENT OF HEALTH, THE DEPARTMENT OF THE ENVIRONMENT,
2 OR THE DEPARTMENT OF AGRICULTURE THAT REGULATES AN OCCUPATION OR
3 PROFESSION AND THAT ISSUES OCCUPATIONAL OR PROFESSIONAL LICENSES,
4 CERTIFICATIONS, OR REGISTRATIONS TO INDIVIDUALS.

5 (D) "LICENSE" MEANS A LICENSE, CERTIFICATE, OR REGISTRATION THAT
6 AN INDIVIDUAL IS REQUIRED TO OBTAIN UNDER THIS ARTICLE, THE AGRICULTURE
7 ARTICLE, THE BUSINESS OCCUPATIONS AND PROFESSIONS ARTICLE, THE
8 BUSINESS REGULATION ARTICLE, THE ENVIRONMENT ARTICLE, OR THE HEALTH
9 OCCUPATIONS ARTICLE BEFORE ENGAGING IN AN OCCUPATION OR A PROFESSION.

10 11-1602.

11 (A) (1) THE DEPARTMENT MAY ESTABLISH A STANDARD
12 APPRENTICESHIP PROGRAM FOR A LICENSED OCCUPATION OR PROFESSION THAT
13 INCLUDES:

14 (I) THE MINIMUM AMOUNT OF TIME THAT AN APPRENTICE
15 MUST SPEND PRACTICING UNDER A LICENSED PROFESSIONAL BEFORE TAKING AN
16 EXAMINATION FOR LICENSURE;

17 (II) A MINIMUM DEMONSTRATED KNOWLEDGE OF THE
18 PROCEDURES, ACTIONS, PROCESSES, AND WORK THAT AN INDIVIDUAL MAY
19 PERFORM UNDER AN OCCUPATIONAL OR PROFESSIONAL LICENSE IN THE STATE
20 FOR THE OCCUPATION OR PROFESSION FOR WHICH AN APPLICANT IS SEEKING
21 LICENSURE; AND

22 (III) THE MINIMUM AMOUNT THAT A LICENSED PROFESSIONAL
23 MAY PAY AN APPRENTICE DURING THE COURSE OF THE APPRENTICESHIP.

24 (2) THE DEPARTMENT MAY CONSIDER INPUT FROM THE APPLICABLE
25 BOARD IN ESTABLISHING A STANDARD APPRENTICESHIP PROGRAM FOR AN
26 OCCUPATION OR A PROFESSION.

27 (3) A STANDARD APPRENTICESHIP PROGRAM ESTABLISHED UNDER
28 THIS SECTION MAY NOT REQUIRE A MINIMUM AGE FOR PARTICIPATION THAT IS
29 GREATER THAN THE LEGAL MINIMUM AGE TO WORK IN THE STATE.

30 (B) (1) A BOARD MAY REQUIRE AN EXAMINATION FOR AN APPRENTICE TO
31 OBTAIN LICENSURE ONLY IF THE BOARD REQUIRES ALL APPLICANTS FOR
32 LICENSURE TO PASS AN EXAMINATION.

33 (2) A BOARD MAY NOT REQUIRE AN APPRENTICE TO ACHIEVE A

HIGHER SCORE ON A LICENSURE EXAMINATION THAN IT REQUIRES FOR ALL OTHER APPLICANTS.

(3) (I) SUBJECT TO SUBPARAGRAPH (II) OF THIS PARAGRAPH, A BOARD MAY REQUIRE A FEE FOR AN APPRENTICE TO OBTAIN A LICENSE ONLY IF THE BOARD REQUIRES ALL APPLICANTS FOR LICENSURE TO PAY A FEE.

(II) THE FEE REQUIRED UNDER THIS PARAGRAPH MAY NOT EXCEED THE FEE THE BOARD REQUIRES ALL APPLICANTS FOR THE LICENSE TO PAY.

(C) THE DEPARTMENT SHALL ADOPT REGULATIONS NECESSARY TO CARRY OUT THIS SUBTITLE.

11-1603.

A STANDARD APPRENTICESHIP PROGRAM ESTABLISHED UNDER THIS SUBTITLE SHALL BE DESIGNED TO ISSUE A TARGETED NUMBER OF OCCUPATIONAL OR PROFESSIONAL LICENSES AS DETERMINED BY THE DEPARTMENT.

11-1604.

ON OR BEFORE DECEMBER 1, 2024, THE DEPARTMENT SHALL ESTABLISH A WORKGROUP, IN CONSULTATION WITH THE MARYLAND DEPARTMENT OF HEALTH, THE DEPARTMENT OF THE ENVIRONMENT, AND THE DEPARTMENT OF AGRICULTURE, TO ESTABLISH GROUP-SPONSORED APPRENTICESHIPS IN EACH OCCUPATION OR PROFESSION FOR WHICH A STANDARD APPRENTICESHIP PROGRAM IS ESTABLISHED UNDER § 11-1602(A) OF THIS SUBTITLE.

11-1605.

THIS SUBTITLE MAY BE CITED AS THE MARYLAND APPRENTICESHIPS IN LICENSED OCCUPATIONS ACT.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act is an emergency measure, is necessary for the immediate preservation of the public health or safety, has been passed by a yea and nay vote supported by three-fifths of all the members elected to each of the two Houses of the General Assembly, and shall take effect from the date it is enacted.

A quarterly
newsletter
published in the
interests of the
health care industry
in the Mid-Atlantic
region

Topics

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Did You Know?

Are IV Businesses “Compounding” Prescriptions?

IV hydration businesses are popping up in major cities across the country, including here in Maryland. Most hydration businesses offer a variety of products to their customers, including infusions of vitamins and other elements promoted to improve health or reduce stress. Since

these businesses are relatively new, they remain largely unregulated.

However, recent guidance from the Food and Drug Administration (FDA) makes it clear that IV hydration businesses need to be aware that some of their activities may be considered to involve the “compounding” of drugs, and thereby require the businesses to comply with a web of federal and state laws and regulations.

A. FDA

The FDA applies certain sanitary and manufacturing requirements to the compounding of drugs. The FDA stated in an October 2021 article that “Drugs” and “Drug products” include IV hydration products and IV vitamins. While not defined in the law, the FDA has consistently stated in guidance that: compounding is the practice in which “ingredients of a drug are combined, mixed, or altered to create a medication tailored to the medical needs of an individual patient”; and adding vitamins to an intravenous solution bag is compounding.

The FDA requires all drugs, including compounded drugs, to meet certain good manufacturing practice standards, labeling requirements, and to be approved by the FDA as a new drug. However, Section 503A of the Food and Drug Act exempts from

Board of Nursing
FDA
USP 797
Board of
Pharmacy

these requirements certain compound drug products that meet certain requirements (FDA Exemption), including:

1. A drug product that is compounded for an identified individual based on a valid prescription order of a prescribing practitioner, and the compounding *is performed by a licensed pharmacist in a licensed pharmacy or a licensed physician*; or

2. A drug product that is compounded *by a licensed pharmacist or physician* and done in limited quantities before receiving a valid prescription but based on a history of receiving valid prescriptions such that a relationship is established between the licensed pharmacist/physician and the individual patient or ordering practitioner.

Certain other requirements also apply to limit the substances that may be used even in an exempt compounding.

Therefore, if IV hydration businesses are compounding drugs (for example, adding vitamins to IV solutions) without using a physician or pharmacist to do the compounding, then these businesses are not exempt from the good manufacturing practice requirements, labeling requirements, and FDA approval process for the compounded drug.

B. United States Pharmacopeia 797

Even if the IV hydration compounding fits into the FDA Exemption, the compounding

must still comply with the USP 797 guidelines for sterile preparations.

The USP 797 guidelines, with changes effective November 1, 2023, establish requirements for compounded sterile preparations (CSPs) which include personnel training and testing, personal hygiene and garbing requirements, facilities and engineering controls including air flow and cleaning, certification, monitoring, equipment and supplies standards, and record keeping requirements.

The guidelines, however, exempt from most of the requirements "Immediate-Use CSPs" and "Preparation Per Approved Labeling".

Immediate-Use CSPs must meet certain requirements, including policies and procedures and staff training, and be for the direct and immediate administration to a patient, including being administered to the patient within four (4) hours of the preparation. If the CSPs meet this exception, then the IV hydration business may not have to comply with the more onerous USP 797 standards, though it will still have to fit into the FDA Exemption.

The exception for Preparation Per Approved Labeling requires that any mixing, reconstituting, or other such acts are performed in accordance with directions contained in approved labeling or supplemental materials provided by the product's manufacturer and the product is prepared as a single dose for an individual patient and the approved labeling contains information for the diluent, the resultant strength, the container closure system, and storage time.

Any mixing of drugs that meets this exception would not be considered compounding. This means that if an IV hydration business purchases its IV cocktails from a manufacturer whose products meet the preceding requirements, the IV hydration business does not need to meet the additional USP 797 requirements nor fit into the FDA Exemption.

C. Maryland State Law

State laws on compounding drugs also impact the regulatory landscape that IV hydration businesses must navigate. In Maryland, there is some confusion regarding how the various state licensing boards will interpret and enforce these State laws.

Maryland law defines the practice of pharmacy as including "compounding" prescription and nonprescription drugs and devices. The law

Topics is published by the Health Care Department of the law firm of **Gordon Feinblatt LLC**, a multidisciplinary team of lawyers with experience in areas of law affecting health care services.

The information contained herein is not intended to provide legal advice or opinion and should not be acted upon without consulting an attorney.

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defines “compounding” to mean “the preparation, mixing, assembling, packing, or labeling of a drug or device[.]”

On July 19, 2023, the Board of Pharmacy at its Board meeting stated “[i]ntroducing vitamins into a sterile intravenous solution bag constitutes compounding. As such, compounding performed by a pharmacist must occur in accordance with USP <797> (under a hood and in a sterile environment). Please contact the respective health boards for standards relating to compounding by other healthcare practitioners.”

However, Maryland regulations governing the practice of nursing also state that a nurse may “[a]dd medications to an intravenous solution” subject to specific education and training requirements. The nursing regulations do not state anything about compliance with USP 797.

Neither the Board of Nursing nor the Board of Pharmacy have issued any clarifying guidance on how these two state laws interact.

D. Conclusion

IV hydration businesses should be aware that, unless the intravenous solution products they purchase from manufacturers come premixed, or are labeled sufficiently with instructions on mixing and meet the USP 797 Preparation Per Approved Labeling exception, a physician or a pharmacist must be engaged to perform the compounding in compliance with the FDA Exemption standards, or the IV hydration business will need to meet the much higher FDA standards for non-exempt compounding, which is likely unrealistic for these new, often small, start-up businesses.

There is also some uncertainty at the State level as to whether nurses who add medications to intravenous solutions are compounding under State law and are required to comply with USP 797 as are compounding pharmacists in Maryland. Accordingly, licensed practitioners may want to reach out to their respective licensing boards to request clarification on how their board regulates the act of compounding for IV hydration.

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New Proposed Merger Guidelines

Recently, the U.S. Department of Justice (DOJ) and Federal Trade Commission (FTC) released Draft Merger Guidelines (Draft Guidelines) outlining various new factors the Agencies will consider when reviewing the legality of mergers and acquisitions.

The Draft Guidelines set forth 13 new frameworks that the Agencies will use to determine whether a merger violates antitrust laws, specifically Section 7 of the Clayton Act. Section 7 prohibits mergers that have an anticompetitive effect (that is, mergers which may substantially stifle competition in a relevant market or create a monopoly).

The Draft Guidelines contain considerable changes from the 2010 Horizontal Merger Guidelines and the 2020 Vertical Merger Guidelines, including an expansion of what is considered an antitrust harm, and significant reductions in the standards for when the Agencies will presume antitrust harm.

This article outlines some of the crucial proposals that are predicted to impact future health care mergers, including notable changes to the regulatory review of vertical and serial mergers (known as “roll-ups”), and a new emphasis on the impact to health care employees.

A. Vertical Mergers

Historically, the Agencies had limited authority to review or challenge vertical mergers. Vertical mergers are mergers between companies within the same supply chain. However, the Draft Guidelines expand the Agencies’ reach over vertical mergers.

For example, under the Draft Guidelines, a challenge may be brought if a merger has the effect of restricting a competitor’s access to sensitive data and information. This could impact mergers between hospitals and health tech companies.

Additionally, vertical mergers can be examined even when the merging companies have less than a 50% market share.

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The Draft Guidelines would also allow the Agencies to consider both prior transactions and the possibility of future transactions when determining anticompetitive effect on a relevant market. Previously, the Agencies would review every transaction separately.

These changes could impact attempts by large hospital systems and private equity companies to acquire smaller physician practices.

B. Emphasis on Employees

There are also changes on the regulatory review of horizontal mergers. Notably, the Draft Guidelines include a requirement that merging companies include the proposed merger's impact on the labor market, specifically physicians and nurses, as part of any required filing under the Hart-Scott-Rodino Act. This new information could be used to support an allegation of anticompetitive harm.

C. Market Share

The Draft Guidelines also create a presumption of antitrust harm if the merged company would have a market share greater than 30%, which is a significant decrease from the previous 50% standard. Without considering overall market concentration, the Draft Guidelines contend that companies with over a 30% market share create an "impermissible threat of undue concentration" to relevant markets.

In practice, this would make it easier for the Agencies to challenge a merger by shifting the onus of proving non-anticompetitive effect onto the health care companies.

D. Conclusion

While the Draft Guidelines are not enforceable law, they offer insight into how the DOJ and FTC plan to review mergers in the future. Many legal experts predict that these guidelines could decelerate the rapid pace of mergers and acquisitions within the health care industry.

Nevertheless, the future impact of these proposed guidelines remains inconclusive when considering the DOJ's and FTC's losing streak in challenging recent merger deals. Whether courts will follow the DOJ's and FTC's new aggressive approach will only be determined as new challenges are brought.

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New CON Regulations

In October 2023, the Maryland Health Care Commission (MHCC or Commission) reviewed and approved for public comment Proposed Final Regulations making significant changes to the Procedural Regulations for Health Care Facilities and Services. This is the latest step in a multi-year process of updating the certificate of need (CON) regulations to conform with significant statutory changes that have occurred since the regulations were last updated.

The following is a summary of the proposed changes that have gone through multiple rounds of informal public comment. The final public comment period closes in January 2024.

A. Post-Approval Requirements for Non-CON Projects

The proposed regulations would require projects that are not required to undergo a full CON review process to comply with many of the post-approval requirements for projects undergoing a full CON review. The Commission insists that this is not a change from its current interpretation of the regulations, and that the proposed new language only serves to clarify an existing requirement. Commentors disagree, arguing that this is a significant change that requires more detailed discussion before adopting the proposed language.

The proposed regulations explicitly require projects that are exempt from CON review, such as conversions of hospitals into free-standing medical facilities and consolidations of health care facilities, to develop a project implementation schedule, provide the Commission with progress reports, make capital expenditure obligations by certain deadlines, and seek approval of certain project changes through the project change request process established for CON projects.

Since it is the Commission's position that this is already required, projects operating under an exemption should be aware that the Commission believes those projects are currently subject to these extra reporting requirements.

Additionally, the proposed regulations allow the Commission to place restrictions on an approved exemption request.

B. Timeline Flexibility

Currently, the regulations establish strict implementation timelines for approved projects that do not provide for the flexibility needed for projects of differing scale. The proposed regulations would require each applicant to propose a reasonable schedule to implement the project in its application.

Additionally, the proposed regulations would allow the Commission to develop guidance for calculating allowable inflation, which is intended to reduce the number of project change requests submitted to the Commission as a result of escalating construction costs.

C. Other Changes

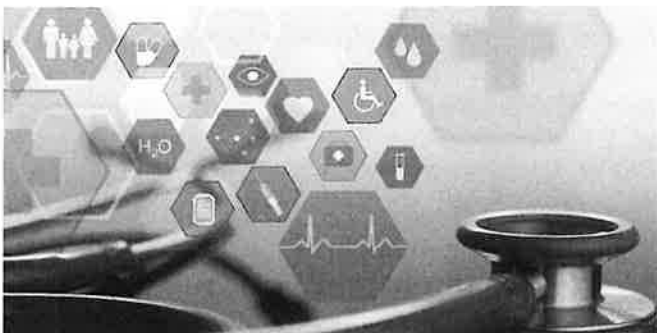
The proposed regulations make additional changes, such as imposing timeliness requirements for the MHCC staff to conduct its completeness review of a CON application, and limiting the rounds of follow up questions that may be asked during the completeness review.

The proposed regulations also limit who qualifies as an interested party, and is thereby able to intervene in an applicant's CON review process and to object to the application. The current regulations do not require that an interested party demonstrate a negative impact to its health care facility. The proposed regulations would require a person who wants to be an interested party to demonstrate that the quality of care at its health care facility would be materially affected, or that the project would result in a substantial depletion of essential personnel or other resources.

Additionally, under the proposed regulations, the Commission will now consider a project's impact on health equity, and the character and competence of applicants when reviewing proposals.

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LLC Operating Agreements

This is the second part of a several part series of articles pertaining to limited liability company operating agreements. This second installment addresses voting rights, distributions, capital accounts, buy-ins and buy-outs.

Many medical practices and other health care enterprises operate as limited liability companies (LLCs), and are, therefore, governed by the LLC's "operating agreement." However, the concepts imbedded in such operating agreements are often foreign or confusing to the members of the LLCs. Accordingly, the purpose of this series of articles is to shed some light on those concepts.

A. Voting

In a member managed company, members vote on every issue that comes before the company, whereas, in a manager managed company, the members only vote on big decisions, such as changes to the operating agreement, adding or removing members, major changes to the business, or the dissolution of the company.

Voting rights can be allocated on a proportional basis, where votes are weighted by the percentage of ownership. They can also be allocated on a per capita basis, where there is one vote per member. Members can structure these voting rights differently for different types of decisions; for instance, day-to-day decisions may be subject to proportional voting, but a decision to dissolve the company may be a per capita vote. Similar voting structures can be applied to board decisions as well.

A member with economic (or profits) interests only will not have voting rights. Those members are only entitled to allocations of income. Owners can use economic interests as an effective strategy for succession planning by awarding economic interests to young members with limited personal capital for investment. Economic interests can also be used to limit the control of the business by inexperienced members.

B. Distributions

Distributions are the shares of profits that go to the owners of the limited liability company.

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However, members pay taxes on their share of company profits, which may or may not equal the distributions they receive from the company. Accordingly, operating agreements often require the company at least to make distributions to the members that are equal to the presumed taxes the members will owe on their share of the profits of the company.

Operating agreements also often provide that the company is to distribute its “available cash” to the members, and the definition of such “available cash” is therefore significant. Such definitions often include the flexibility that a company may create a reserve, which will not be distributed, and, therefore, it is very important to know who has the power to set applicable reserves.

Similarly, it is important to know the frequency of the distributions of available cash, and, again, who has the power to determine such frequency.

Distributions are typically scheduled in the operating agreement, with some companies opting to provide regular distributions over the course of a tax year, and others choosing to provide a single payment at year end.

If a company chooses regular distributions, there should be language in the operating agreement allowing the company to make adjustments to the draw amount or otherwise require a true-up should the budgeted draw exceed the company’s actual cash flow.

C. Capital Accounts

A capital account is an account used for tracking individual member investments in the company. The operating agreement should include a schedule of the owners and their initial capital contributions. Capital accounts are increased by additional contributions and profits, and decreased by losses and distributions.

Also, in lieu of making cash contributions, some companies will place a value on a member’s non-financial contributions, such as lending their name and reputation to the company, or the member’s intended skills and labor (that is, “sweat equity”) during the start-up phase.

When a company is dissolved, the balance of the capital accounts are distributed to respective members, but only after the satisfaction of the company’s liabilities.

D. Buy-Ins

During the lifecycle of any long-standing company, there will be changes in ownership. Members should consider what the purchase standards should be for new members. To bring on members, the company will need to find a balance between company value, and the purchasing power of a potential member.

The purchase price for membership is typically referred to as a buy-in. A buy-in may be structured as a one-time payment, or structured subject to vesting. Vesting refers to a conveyance of rights over time during which a member eventually gains a full ownership interest, distribution rights, and termination rights.

For example, if a new member is staggering their payments over a five-year period, their ownership interest could be vested at 20% during each year of that five-year period. Vesting membership can make it easier for young doctors to achieve ownership when their own cash flow may be limited by financial considerations such as student loans.

E. Buy-Outs

Conversely, the applicable operating agreement should address what happens when members want to leave the company or retire, and allow or require the company to buy back the departing member’s interest, or allow or require the remaining members to acquire that interest.

When a member leaves a company, the purchase terms for acquiring their interest in the company are referred to as a buy-out. As with a buy-in, these can be structured as a one-time payment or as payments over time.

If the buy-out occurs over time, there are two typical structures to consider. The first is when the departing member gives up their entire interest at once, but the payments are made over time subject to a promissory note. The second is when the departing member’s ownership interest is sold over an extended period of time, essentially reverse vesting. This is more common when there is a planned retirement of a member, rather than other variations of departure.

If the buy-out is funded by the company, the operating agreement should address whether the non-departing members are required personally to guaranty any deferred payments.

Of course, the operating agreement should also address the price being paid for the departing member's interest, which could, for example, be the member's capital account, a value based on the company's cash or accrual or adjusted balance sheet, a multiple of past annual distributions or an appraisal.

Departures can also be voluntary or involuntary. In a voluntary departure, a member and the company jointly decide it is time for the member to leave. This can be tied to a retirement age, or some other non-confrontational situation. When a member leaves voluntarily, with the approval of the company or in accordance with the operating agreement, he or she is typically paid out for the full value of their ownership interest.

Involuntary departures occur when a member leaves abruptly or the company decides to force the member out. This can be tied to bad behavior, such as breaching fiduciary duties or losing a medical license. Types of bad behavior should be specified in the operating agreement to clearly define what is considered untenable. When a member leaves involuntarily, he or she can be paid out at a discounted rate, if and only if, the operating agreement clearly stipulates the terms of that discount.

Additionally, under Maryland law, if a member is terminated but the operating agreement does not specifically allow termination, that member becomes an economic interest holder in the company. An economic interest holder does not have voting rights, but is still entitled to the full value of distributions based upon their ownership interest.

Health care limited liability companies should also include language in their operating agreements addressing continued malpractice insurance coverage of departing members. Tail coverage can be expensive, especially for certain specialists. The company may want to require that departing members maintain malpractice insurance after their departure; alternatively, the company may want to offer to cover tail coverage for retiring members, but not for those who are departing voluntarily or involuntarily.

The operating agreement should also address whether a departing member may sell their interest to an unrelated third party.

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Did You Know?

Nursing Home Contracts: Did you know that the Illinois Supreme Court recently ruled that an arbitration clause in a nursing home contract was not available to resolve a claim brought by the decedent's estate, where the nursing home contract contained a termination-on-death clause. In *Clanton v. Oakbrook Healthcare Centre, Ltd.*, the court held that where a contract contains a termination-on-death clause, the entire contract is terminated unless certain clauses are specifically exempt.

Medicare Advantage Preemption: Did you know that the California Supreme Court recently found that the statutory language of Medicare Part C (Medicare Advantage) contains an express preemption of "any state law or regulation" that concerns Medicare Advantage plans? The court held in *Quishenberry v. UnitedHealthcare* that the federal preemption applied to both state statutory and common law duties. This is a broader interpretation than other federal standards that only preempt state law when the state law differs from the federal standards.

Corporate Practice of Medicine: Did you know that a federal district court in New York recently held that medical clinics owned by licensed physicians may violate criminal federal health care fraud laws where the actual ownership and control of the clinic is vested in non-physicians? In *U.S. v. Pierre*, the court found that physicians made false statements to automobile insurers by submitting claims from clinics that included attestations that the clinic was in compliance with New York law requiring that medical practices be owned by licensed physicians. The clinics were actually owned and operated by non-physicians who paid licensed physicians to "own" the clinics on paper. The physicians had no real understanding of the clinics and their operations. This decision is significant since management services arrangements are often used to circumvent state corporate practice of medicine laws. Therefore, at least in New York, physician owner(s) should retain control of such medical practices.

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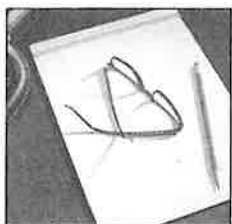
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Topics

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Maryland Regulatory News

1. The Maryland Health Services Cost Review Commission (HSCRC) was tasked with drafting new regulations to implement changes to the State law that requires hospitals to provide financial assistance with respect to bills for services provided to low-income patients. The new law requires hospitals to provide income-based payment plans to all patients, regardless of the patient's income. At its October 2023 meeting, the HSCRC approved a new draft of the guidelines to be published in the Maryland Register following which the HSCRC will be accepting written public comments on the draft guidelines. The new draft permits hospitals to offer both income-based and non-income-based payment plans, prohibits limiting the provision of free care to the hospital's service area residents, and clarifies

that financial assistance cannot be limited to urgent and emergent care.

2. The Maryland Department of Labor released updated information in September about the implementation of the new Family and Medical Leave insurance that will be required to be provided by all employers with 15 or more workers. The State Plan (an alternative to purchasing private insurance) will require a contribution rate of 0.9% of covered wages and will be equally divided between employees and employers contributing to the State Plan. Employers choosing to purchase private insurance or to self-insure may not require their employees to contribute more than they would be required to contribute to the State Plan (0.45% of covered wages).

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Coming in
Future
Issues

- Operating Agreements
- Negotiated Drug Prices
- Doctor Unions