BOARD OF PODIATRIC MEDICAL EXAMINERS

OPEN SESSION MEETING VIA GOOGLE MEET

AGENDA

May 09, 2024

Location: Google Meet meet.google.com/sgp-cccp-kqa

Join by phone: (US) +1 484-469-5704 PIN: 938 021 451

A. ORDER OF BUSINESS

1. **Call to Order- Roll Call**
2. **Approval of minutes from March 14, 2024, meeting** **Tab A**

B. BOARD PRESIDENT'S REPORT

C. EXECUTIVE DIRECTOR'S REPORT

D. OLD BUSINESS:

1. **Update on Collection of APMA data for Podiatrist Representation by County**

   Report on data collection from Mr. Bloch.

2. **Update on HB 1072/SB 1201- Occupational and Professional Licensing- Military Training and Military Spouse**

   Final update on the Bill.

E. NEW BUSINESS:

1. **End of Session Report- 2024** **Tab B**
2. **Discussion on Podiatric X-Rays and Delegation of Duties to Unlicensed Professionals** **Tab C**
3. **New License Approval**
   a. **Robert Toomey, DPM**
   b. **Chang Kim, DPM**
   c. **Tuhin Muhkerjee, DPM**

d. Nam Tran, DPM
e. David Goodman, DPM
f. Riasat Ali, DPM

4. Topics Newsletter- Spring 2024 Tab D

F. ADJOURNMENT

A

BOARD OF PODIATRIC MEDICAL EXAMINERS

OPEN SESSION MEETING VIA GOOGLE MEET

PUBLIC MEETING MINUTES

March 14, 2024

Location: Google Meet meet.google.com/jve-iomd-ofe

Join by phone: (US) +1 413-402-0022 PIN: 630082470

The Public Meeting commenced at 1:04pm, 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. was absent.

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.

Representing MPMA: Dr. Jay Lebow, MPMA Member. MPMA: Mr. Richard Bloch, Esq., Executive Director and Chief Counsel, was absent.

Guests: Zakiyah Holmes- MDH, and Hummira Abawi, DPM representing self.

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 February 8, 2024, meeting.**

   The meeting minutes from the February 8, 2024, public meeting, were approved unanimously, as submitted.

B. BOARD PRESIDENT'S REPORT

Dr. Duggirala had no report at this time.

C. EXECUTIVE DIRECTOR'S REPORT

Ms. Schwartz shared that the legislative session is ongoing. All relevant legislation to the Board has been posted and discussed. Additionally, Ms. Schwartz shared that the Board has seen an increase in Scope of Practice interpretation requests. The Board responds to these inquiries directly referencing the Podiatry Act.

D. OLD BUSINESS:

1. **Update on HB 642 - Apprenticeships in Licensed Occupations Act of 2024**

   Ms. Schwartz shared that HB 642- Apprenticeships in Licensed Occupations Act of 2024, was withdrawn by the sponsor. The Board of Physicians presented a very strong opposition during the hearing on February 15, 2024. The Bill was withdrawn on February 19, 2024, due to additional Boards also opposing this bill. Additionally, there was a lack of an acceptable pathway to license a person lacking the educational and professional training required for licensure.

2. **Update on HB 581/SB 472- State Government - Permits, Licenses, and Certificates Processing (Transparent Government Act of 2024)**

   Ms. Schwartz shared that HB 581/SB 472- State Governments- Permits, Licenses, and Certificates Processing (Transparent Government Act of 2024) proposes to change and update State Government processes regarding licensure to ensure fluidity amongst the Boards. Either the House or the Senate Bill is expected to pass.

NEW BUSINESS:

1. **Review of Scope of Practice Inquiry Submitted to the Board Regarding Billing Codes for Varithena Procedures**

   The Board reviewed the scope of practice inquiry regarding billing codes for Varithena procedures. Ms. Lim shared that COMAR 16-101 should be referenced for all inquiries regarding scope of practice inquiries submitted to the Board, including the billing codes for Varithena Procedures. The Boards Statute 16-101 of the Podiatry Act states:

   "(f) Practice podiatry.-

   (1) 'Practice podiatry' means to diagnose or surgically, medically, or mechanically treat any ailment of the human foot or ankle, or any ailment of the anatomical structures that attach to the human foot.

   Ms. Schwartz questioned if the Podiatry Practice Act should be referenced regardless of the relevancy of an inquiry. Ms. Lim stated that the Board does not issue legal advisory opinions and a practitioner can contact a health care attorney for such.

2. **SB 1072/HB 1201- Occupational and Professional Licensing- Military Training and Military Spouse**

Ms. Schwartz shared that SB 1072/ HB 1201- Occupational and Professional Licensing-Military training and Military Spouse were similar to previously submitted bills that have passed successfully. Ms. Schwartz emphasized that licensees must meet the minimum criteria of the Board's licensing requirements, and according to the MBPME's statute, temporary practicing licenses are not being issued. The Board will track the Bills' progress.

3. **Maryland Loan Repayment Program for Healthcare Providers**

Ms. Schwartz shared that she was contacted by Kimberly Hines, Director of the Office of Population Health Improvement, regarding the qualifications of a podiatrist to apply for the loan repayment program for physicians. The meeting was held in conjunction with the Board of Physicians' Policy Analyst, to determine if a podiatrist qualifies for such a loan. Upon discussion, it was determined that due to the program being federally funded only physicians, physician assistants and nurses are eligible for the loan repayment program. Ms. Schwartz emphasized that the Federal and Maryland laws would have to change in order that other professionals such as podiatrists, dentists and physical therapists, just to name a few, would be able to qualify for the loan repayment program.

4. **NPDB Insights**

NPDB highlights were shared for informational purposes.

Other

Dr. Umezurike shared that there is an outage in Change Healthcare. Change Healthcare is a clearing house used across various specialties that processes claims and provides payments for insurance companies. The outage at Change Healthcare has taken place for three weeks. Dr. Umezurike emphasized that insurance claims have not been processed and remitted to agencies. Dr. Umezurike shared that the outage should be restored by next week; however, an exact time frame is unknown.

Ms. Schwartz shared that Mr. Bloch is seeking to collect statistics on the number of practicing podiatrists in Maryland, according to specific counties. Ms. Schwartz questioned the reason for such a request. In Mr. Bloch's absence, discussion regarding the collection of the statistics was moved to the next Open Session meeting in May.

F. ADJOURNMENT

With no further business, the Public Session Meeting concluded at 1:36 PM.

Respectfully submitted by Eva Schwartz, Executive Director, Signature and date__
Elizabeth Kohlhepp, Deputy Executive Director, Signature and date___
Signature by Frona Kroopnick, Board Secretary/Treasurer:___

B

MARYLAND
Department of Health

Pre-Proposal Concept Paper – 2025 Departmental Legislation

Administration:
Title of Proposed Legislation:
Statutes to be Amended or Added:
Priority Order:
Date:

Part I: Concept: Please explain what this proposal is seeking to achieve and why it is necessary or desirable. This section should answer the questions below and should be the focal point of your concept paper.

1. What will this proposal do (i.e., what statutory changes will you make)?
2. How will these changes be different from current law (e.g., is this a policy change, it is clarifying current law, is it repealing obsolete language)?
3. How will these changes improve the status quo (e.g., does it improve the administrative functioning of the Department, does it improve the health of Marylanders in a specific way, does it bring Maryland into conformity with federal law)?

Note – the Secretary will approve a concept as it is presented in this document; i.e., approval for a proposal is limited to what is in the concept paper. So, please make sure that your concept paper includes all items to be included in the bill, and includes a strong rationale for those items.

Part II: Fiscal and Operational Impact: Please explain the fiscal and operational impact of this legislation on the following:

1. The Department
2. Other State agencies or local governments
3. Small businesses

Part III: Legislative Strategy: Please provide context for this proposal by answering the following questions:

1. Prior introductions: Identify and describe any prior attempts to enact legislation similar to the one proposed.
2. Anticipated support or opposition: Describe any likely support or opposition to the proposal by stakeholder groups and interested parties.
3. Stakeholder strategy: Describe the administration's plan to build stakeholder support and minimize opposition to the proposal.

Pre-Proposal Concept Papers should be 2-5 pages in length.

END OF SESSION REPORT — 2024

Bills of Interest

HB 34/SB 204 — *Interstate Social Work Licensure Compact*

STATUS: The HB passed the House but did not get voted out of the Senate Finance Committee. The SB did not get voted out of the Senate Finance Committee.

SYNOPSIS: Entering into the Social Work Licensure Compact for the purpose of authorizing regulated social workers who hold interstate compact licenses to practice social work in member states; establishing requirements for multistate licensure; establishing the Social Work Licensure Compact Commission; and providing for withdrawal from the Compact.

HB 146/SB 221 — *Health Occupations Boards – Reciprocal Licensure and Certification*

STATUS: The HB and SB passed. To be effective 7/1/24.

SYNOPSIS: Authorizing certain health occupations boards to adopt regulations establishing reciprocity for individuals licensed or certified in another state.

HB 152 — *Department of the Environment - Study on Deathcare and Funeral Practices*

STATUS: Passed both chambers but did not get voted out of the Conference Committee.

SYNOPSIS: Requiring the Department of the Environment, in consultation with the Maryland Department of Health and the Maryland Department of Labor, to conduct a study of the environmental and public health impacts of deathcare and funeral practices in the State; and requiring the Department to report its findings and recommendations to the Governor and the General Assembly on or before October 1, 2025.

HB 175/SB 54 — *Occupational Licensing and Certification – Criminal History – Prohibited Disclosures and Predetermination Review Process*

STATUS: The HB passed the House but did not get voted out of the Senate Finance (also Education, Energy, and the Environment) Committee. The SB did not get voted out of the Senate Finance (also Education, Energy, and the Environment) Committee.

SYNOPSIS: Altering certain provisions of law regarding the prohibition on certain departments of State government from denying an occupational license or certificate to an applicant solely on the basis of the criminal history of the applicant by prohibiting a department from requiring disclosure of certain actions on an application and establishing a predetermination review process; authorizing a department to change a criminal history review fee of no more than $100 or to waive the fee under certain circumstances; etc.

HB 269 *Criminal Procedure - Disclosure of Expunged Records - Alterations*

STATUS: Did not get voted out of the House Judiciary Committee.

SYNOPSIS: Clarifying that refusal by a person to disclose information about criminal charges that have been expunged may not be the sole reason for a unit, an official, or an employee of the State or political subdivision of the State to deny the person's application for a license, permit, registration, or governmental service or for an educational institution to expel or refuse to admit the person.

HB 378/SB 330 *State Board of Dietetic Practice - Dietitian-Nutritionists - Application Requirements*

STATUS: The HB passed with amendments. The SB did not get voted out of the Senate Finance Committee. To be effective 7/1/24.

SYNOPSIS: Requiring that an individual shall have received at a minimum a degree from a college or university accredited by an educational accrediting association as required by the Commission on Dietetic Registration to be licensed as a dietitian-nutritionist.

HB 381/SB 175 *State Board of Examiners in Optometry - Criminal History Records Checks*

STATUS: The HB and SB passed with amendments. To be effective 10/1/24.

SYNOPSIS: Requiring an applicant for a license to practice optometry and certain applicants for the renewal of a license to submit to a criminal history records check obtained from the Criminal Justice Information Central Repository of the Department of Public Safety and Correctional Services; and providing that information obtained from the Central Repository is confidential, may not be redisseminated, and is to be used only for licensing purposes.

HB 464/SB 795 *Health Occupations – Practice Audiology – Definition*

STATUS: The HB and SB passed with amendments. To be effective 10/1/24.

SYNOPSIS: Altering the definition of "practice audiology" for the purposes of certain provisions of law governing the licensure and regulation of audiologists.

HB 581/SB 472 *State Government - Permits, Licenses, and Certificates - Processing (Transparent Government Act of 2024)*

STATUS: The HB and SB passed. To be effective 7/1/24.

SYNOPSIS: 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 to submit the catalog to the Governor on or before October 1, 2024; requiring certain departments and independent units to post certain completed information relating to permits, licenses, and certificates on the website of the department or independent unit by October 1, 2025; establishing the Government Efficiency Commission; etc.

HB 628/SB 409 *Health Occupations - Clinical Marriage and Family Therapists - Reciprocal Licensure Requirements*

STATUS: The HB and SB passed. To be effective 10/1/24.

SYNOPSIS: Altering the licensure requirements that the State Board of Professional Counselors and Therapists may waive, and the circumstances under which the requirements may be waived, for applicants for a license to practice clinical marriage and family therapy in the State who are licensed or certified to practice clinical marriage and family therapy in another state, territory, or jurisdiction.

HB 642/SB 1185 *Apprenticeships in Licensed Occupations Act of 2024*

STATUS: The HB was withdrawn in the House and the SB did not get voted out of the Senate Rules Committee.

SYNOPSIS: 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, pass a certain examination, and pay a certain fee; authorizing the Maryland Department of Labor to develop a standard apprenticeship program for a licensed occupation or

profession; and establishing a workgroup to establish group-sponsored apprenticeships in certain professions.

HB 755/SB 106 — *State Board of Social Work Examiners - Board Membership and Certified Social Worker Licenses*

STATUS: The HB and SB passed. To be effective 6/1/24.

SYNOPSIS: Altering the membership of the State Board of Social Work Examiners; and repealing obsolete references to certified social worker licenses.

HB 809 — *Members of Boards, Committees, Commissions, Task Forces, or Workgroups – Removal or Suspension*

STATUS: Passed. To be effective 10/1/24.

SYNOPSIS: Providing that a member of a board, committee, commission, task force, or workgroup created by State law may be removed or suspended for misconduct, incompetence, neglect of duties, or other good cause by the individual or entity that appointed the member under certain circumstances; authorizing the removal or suspension of an appointed member only after consultation with the chair of the board, committee, commission, task force, or workgroup and the member has been given an opportunity to be heard regarding the removal or suspension; etc.

HB 874/SB 613 — *State Board of Long-Term Care Administrators - Requirements for Assisted Living Managers*

STATUS: The HB and SB passed with amendments. To be effective 7/1/24.

SYNOPSIS: Extending, from October 1, 2024, to July 1, 2026, the date by which an individual must be licensed by the State Board of Long-Term Care Administrators before practicing as an assisted living manager in the State; altering the requirements for the manager training course that certain assisted living managers are required to complete; altering the requirements for serving as an interim assisted living manager; and requiring the Board to submit certain reports on assisted living managers to certain committees of the General Assembly.

HB 892 — *Criminal Law - Benefits Exploitation*

STATUS: Passed the House but did not get voted out of the Senate Judicial Proceedings Committee.

SYNOPSIS: Prohibiting a person from knowingly recruiting, harboring, transporting, or obtaining an individual for the purpose of appropriating the government benefits of an individual for the benefit of the person or another through deception, coercion, exploitation, isolation, or any other means; prohibiting a person from aiding, abetting, or conspiring with one or more persons to violate a certain provision of the Act; establishing that a violation of the Act is a felony; etc.

HB 959 *Health Occupations - Certified Dialysis Technicians - Continuing Education Requirement*

STATUS: Passed. To be effective 6/1/24.

SYNOPSIS: Altering the continuing education requirement for certified dialysis technicians to require 3 hours of continuing approved by the Board.

HB 1120/SB 794 *State Board of Social Work Examiners – Continuing Education Programs – Approval of Authorized Sponsors*

STATUS: Withdrawn in the House and Senate.

SYNOPSIS: Requiring the State Board of Social Work Examiners to establish a process to review and approve certain persons as authorized sponsors of social work continuing education programs, subject to a requirement that at least one pathway for approval does not require an applicant to have the approval of a national or regional organization.

HB 1168/SB 1028 *Human Remains - Alkaline Hydrolysis and Natural Organic Reduction (Green Death Care Options Act)*

STATUS: The HB and SB passed with amendments. To be effective 10/1/24.

SYNOPSIS: Establishing a regulatory system for reduction operators and reduction facilities; establishing requirements and prohibitions related to the performance of alkaline hydrolysis and natural organic reduction and the disposition of hydrolyzed or soil remains by certain facilities; prohibiting a person from using or disposing of soil remains produced by natural organic reduction in a certain manner, including by using the soil to grow food for consumption by humans or livestock; etc.

HB 1201/SB 1072 *Occupational and Professional Licensing - Military Training and Military Spouses*

STATUS: The HB did not get voted out of the House Economic Matters Committee and the SB did not get voted out of the Education, Energy, and the Environment Committee.

SYNOPSIS: Requiring an occupational licensing board to issue a license, certificate, permit, or registration to an applicant who is military trained or who is a military spouse if the applicant meets certain requirements; requiring an occupational licensing board to consider certain types of experience for a certain calculation; and authorizing an occupational licensing board to issue a temporary license, certificate, permit, or registration under certain circumstances.

HB 1260/SB 926 *State Government - Permits, Licenses, and Certificates - Reimbursement*

STATUS: The HB did not get voted out of the House HGO Committee and the SB did not get voted out of the Education, Energy, and the Environment Committee.

SYNOPSIS: Requiring the Attorney General to give notice to State agencies and the public when a court orders that the State may not require a person to possess a specified permit, license, or certificate; and requiring State agencies to reimburse issuance and renewal costs for such permits, licenses, and certificates.

HB 1285/SB 931 *Workers' Compensation - Rehabilitation Practitioners - Licensed Social Workers*

STATUS: The HB passed the House but did not get voted out of the Senate Finance Committee. The SB did not get voted out of the Senate Finance Committee.

SYNOPSIS: Authorizing certain licensed social workers to register as a rehabilitation practitioner; and authorizing a licensed certified social worker-clinical to provide evaluation services for workers' compensation claims related to permanent impairments involving a behavioral or mental disorder.

HB 1289 *State Board of Social Work Examiners - Practice Social Work - Definition and Scope of Authority*

STATUS: Did not get voted out of the House HGO Committee.

SYNOPSIS: Altering the definition of "practice social work" to clarify the types of assessments that may be performed by a licensee, add biopsychosocial treatment as a treatment option, and clarify the scope of practice for individuals licensed as certified social worker-clinical; and

authorizing the Board of Social Work Examiners to adopt regulations regarding requirements for engagement in additional acts of social work otherwise authorized by law but not specifically by the Board.

HB 1292

Optometrists - Prescriptions for Glasses and Contact Lenses - Pupillary Distance Measurement

STATUS: This bill was withdrawn.

SYNOPSIS: Requiring the prescribing optometrist to include, in each prescription for glasses or contact lenses provided to a patient, the pupillary distance measurement at no additional cost to the patient.

HB 1327

Maryland Department of Health - Body Altering Aesthetics Advisory Committee

STATUS: Passed the House but did not get voted out of the Senate Finance Committee.

SYNOPSIS: Establishing the Body Altering Aesthetics Advisory Committee within the Maryland Department of Health to study whether the current health occupations licensing and certification system adequately regulates the body altering aesthetics industry in the State; and requiring the Advisory Committee to submit interim findings by December 1, 2024, and a final report with any recommended regulatory or legislative changes by December 1, 2025.

HB 1331

Health Insurance - Massage Therapy - Required Coverage and Prohibited Cost Sharing

STATUS: This bill was withdrawn.

SYNOPSIS: Requiring certain insurers, nonprofit health service plans, and health maintenance organizations to provide coverage for massage therapy; and prohibiting the insurers, nonprofit health service plans, and health maintenance organizations from imposing a copayment, coinsurance, or deductible requirement on coverage for massage therapy.

HB 1339/SB 778

Health Insurance - Hearing Aids for Adults - Coverage

STATUS: The HB and SB passed. To be effective 1/1/25.

SYNOPSIS: Requiring insurers, nonprofit health service plans, and health maintenance organizations that provide certain health insurance benefits under certain insurance policies or contracts to provide certain coverage for

certain hearing aids for adults; authorizing a limit on the benefit payable of $1,400 per hearing aid every 36 months; and authorizing an insured or enrollee to choose a certain hearing aid and pay a certain amount for the hearing aid without financial or contractual penalty to the provider of the hearing aid.

HB 1374

Environment - Crematory - Setback Requirements and Permits

STATUS: Did not get voted out of the House Environment and Transportation Committee.

SYNOPSIS: Prohibiting a person from locating a new crematory within 1,000 feet of an assisted living or nursing facility, a property that primarily serves children, or a residential property that is designed primarily for human habitation; and prohibiting the Department of the Environment from issuing a certain permit to a crematory under certain circumstances.

HB 1476/SB 714

State Board of Examiners for Audiologists, Hearing Aid Dispensers, Speech-Language Pathologists, and Music Therapists - Appointment of Members

STATUS: The HB and SB passed. To be effective 10/1/24.

SYNOPSIS: Requiring the Governor to appoint the licensed audiologist members to the State Board of Examiners for Audiologists, Hearing Aid Dispensers, Speech-Language Pathologists, and Music Therapists from a list submitted by the Maryland Academy of Audiology rather than by the Board.

HB 1497

State Board of Massage Therapy Examiners - Scope of Practice, Reinstatements, and Examinations by Health Care Providers

STATUS: Passed with amendment. To be effective 7/1/24.

SYNOPSIS: Altering the definition of "practice massage therapy" to include, subject to certain education and training requirements, instrument-assisted soft tissue manipulation techniques that enhance or imitate manual techniques; altering the circumstances under which the State Board of Massage Therapy Examiners is required to reinstate a license or registration; and requiring the Board to require a licensee or an applicant to submit to an examination by a health care provider under certain circumstances.

HB 1498

State Board of Massage Therapy Examiners - Aiding or Abetting Unauthorized Practice – Prohibition

STATUS: Passed. To be effective 7/1/24.

SYNOPSIS: Prohibiting a person from aiding or abetting the unauthorized practice of massage therapy; and providing penalties for a first violation of the Act of a fine of up to $5,000 or imprisonment not to exceed 1 year and for a subsequent offense, a fine of up to $20,000 per day or imprisonment not to exceed 5 years.

SB 3

Health Occupations - Service Members, Veterans, and Military Spouses - Temporary Licensure, Certification, Registration, and Permitting

STATUS: Did not get voted out the Senate Finance Committee.

SYNOPSIS: Requiring health occupations boards to issue an expedited temporary license, certificate, registration, or permit to a service member, veteran, or military spouse who meets certain requirements; requiring each health occupations board to include a check-off box prominently on each license, certification, or registration application form; requiring the Maryland Department of Health to publish prominently on its website information about the expedited licensing process and any assistance provided; etc.

SB 222

State Board of Environmental Health Specialists – Quorum, Examination, and Apprenticeships

STATUS: Passed. To be effective 10/1/24.

SYNOPSIS: Clarifying that a quorum of the State Board of Environmental Health Specialists consists of a majority of appointed members; altering the circumstances under which an applicant for licensure is qualified to take the examination by adding completion of an apprenticeship approved by the Board as an alternative to obtaining experience in an environmental health specialist-in-training program; and authorizing the Board to approve an examination provider to administer the examination.

SB 236

State Acupuncture Board – Sunset Extension

STATUS: Passed with an amendment. To be effective 7/1/24.

SYNOPSIS: Continuing the State Acupuncture Board in accordance with the provisions of the Maryland Program Evaluation Act (sunset law) by extending to July 1, 2030, the termination provisions relating to the statutory and regulatory authority of the Board.

SB 237

State Board for Certification of Residential Child Care Program Professionals - Sunset Extension

STATUS: Passed with an amendment. To be effective 7/1/24.

SYNOPSIS: Continuing the State Board for Certification of Residential Child Care Program Professionals in accordance with the provisions of the Maryland Program Evaluation Act (sunset law) by extending to July 1, 2030, the termination provisions relating to the statutory and regulatory authority of the Board.

SB 238

State Board of Dietetic Practice – Sunset Extension

STATUS: Passed with an amendment. To be effective 7/1/24.

SYNOPSIS: Continuing the State Board of Dietetic Practice in accordance with the provisions of the Maryland Program Evaluation Act by extending to July 1, 2030, the termination provisions relating to the statutory and regulatory authority of the Board.

SB 239

State Board of Occupational Therapy Practice – Sunset Extension

STATUS: Passed with an amendment. To be effective 7/1/24.

SYNOPSIS: Continuing the State Board of Occupational Therapy Practice in accordance with the provisions of the Maryland Program Evaluation Act by extending to July 1, 2030, the termination provisions relating to the statutory and regulatory authority of the Board.

SB 240

State Board of Examiners in Optometry – Sunset Extension

STATUS: Passed with an amendment. To be effective 7/1/24.

SYNOPSIS: Continuing the State Board of Examiners in Optometry in accordance with the provisions of the Maryland Program Evaluation Act (sunset law) by extending to July 1, 2030, the termination provisions relating to the statutory and regulatory authority of the Board.

SB 241

State Board of Examiners of Psychologists - Sunset Extension

STATUS: Passed with an amendment. To be effective 7/1/24.

SYNOPSIS: Continuing the State Board of Examiners of Psychologists in accordance with the provisions of the Maryland Program Evaluation Act (sunset law) by extending to July 1, 2030, the termination provisions relating to the statutory and regulatory authority of the Board.

SB 242

State Board of Social Work Examiners - Sunset Extension

STATUS: Passed with amendments. To be effective 7/1/24.

SYNOPSIS: Continuing the State Board of Social Work Examiners in accordance with the provisions of the Maryland Program Evaluation Act by extending to July 1, 2030, the termination provisions relating to the statutory and regulatory authority of the Board; and requiring the Board, by December 1, 2024, to report to certain committees of the General Assembly information from the preceding 6-month period on processing times for license issuance and renewal, complaint resolution times, and the rate of compliance with certain requirements.

SB 243

State Board of Professional Counselors and Therapists - Behavior Analyst Advisory Committee - Sunset Extension

STATUS: Passed. To be effective 7/1/24.

SYNOPSIS: Continuing the Behavior Analyst Advisory Committee within the State Board of Professional Counselors and Therapists in accordance with the provisions of the Maryland Program Evaluation Act (sunset law) by extending to July 1, 2026, the termination provisions relating to the statutory and regulatory authority of the Committee.

SB 257

State Board of Physical Therapy Examiners - Sunset Extension

STATUS: Passed with an amendment. To be effective 7/1/24.

SYNOPSIS: Continuing the State Board of Physical Therapy Examiners in accordance with the provisions of the Maryland Program Evaluation Act by extending to July 1, 2030, the termination provisions relating to the statutory and regulatory authority of the Board.

SB 893

Environment - Siting Requirements for Crematories and Crematory Incinerators - Areas III and IV

STATUS: Did not get voted out of the Education, Energy, and the Environment Committee.

SYNOPSIS: Prohibiting a person from locating a new crematory or a property with a crematory incinerator within 1,000 feet of certain properties in Areas III and IV of the State; and prohibiting the Department of the Environment from issuing a certain permit to a crematory or a property with a crematory incinerator under certain circumstances.

Statutes Text

Article - Health Occupations

§14–306. IN EFFECT

(a) To the extent permitted by the rules, regulations, and orders of the Board, an individual to whom duties are delegated by a licensed physician may perform those duties without a license as provided in this section.

(b) The individuals to whom duties may be delegated under this section include any individual authorized to practice any other health occupation regulated under this article or § 13–516 of the Education Article.

(c) The Board shall adopt rules and regulations to delineate the scope of this section. Before it adopts any rule or regulation under this section, the Board shall invite and consider proposals from any individual or health group that could be affected by the rule or regulation.

(d) (1) If a duty that is to be delegated under this section is a part of the practice of a health occupation that is regulated under this article by another board, any rule or regulation concerning that duty shall be adopted jointly by the Board of Physicians and the board that regulates the other health occupation.

(2) If the two boards cannot agree on a proposed rule or regulation, the proposal shall be submitted to the Secretary for a final decision.

(e) Except as otherwise provided in this section, an individual may perform X–ray duties without a license only if the duties:

(1) Do not include:

(i) Computerized or noncomputerized tomography;

(ii) Fluoroscopy;

(iii) Invasive radiology;

(iv) Mammography;

(v) Nuclear medicine;

(vi) Radiation therapy; or

(vii) Xerography;

(2) Are limited to X–ray procedures of the:

(i) Chest, anterior–posterior and lateral;

(ii) Spine, anterior–posterior and lateral; or

(iii) Extremities, anterior–posterior and lateral, not including the head; and

(3) Are performed:

(i) By an individual who is not employed primarily to perform X–ray duties;

(ii) In the medical office of the physician who delegates the duties; and

(iii) 1. By an individual who, before October 1, 2002, has:

A. Taken a course consisting of at least 30 hours of training in performing X–ray procedures approved by the Maryland Radiological Society in consultation with the Maryland Society of Radiologic Technologists; and

B. Successfully passed an examination based on that course that has been approved by the Maryland Radiological Society in consultation with the Maryland Society of Radiologic Technologists; or

2. By a licensed physician assistant who has completed a course that includes anterior–posterior and lateral radiographic studies of extremities on at least 20 separate patients under the direct supervision of the delegating physician or radiologist using a mini C–arm or similar low–level radiation machine to perform nonfluoroscopic X–ray procedures, if the duties:

A. Include only the X–ray procedures described in paragraph (2)(iii) of this subsection; and

B. Are performed pursuant to a Board–approved delegation agreement that includes a request to perform advanced duties under § 15–302(c)(2) of this article.

(f) (1) In accordance with regulations adopted by the Board, a licensed physician may delegate duties to a registered cardiovascular invasive specialist assisting in the physician's performance of fluoroscopy if:

(i) The delegated duties are limited to a cardiac catheterization procedure performed in a hospital cardiac catheterization laboratory;

(ii) The physician is physically present and personally directs each act performed by the registered cardiovascular invasive specialist;

(iii) The registered cardiovascular invasive specialist has completed the training and education and has the experience required by regulations adopted by the Board; and

(iv) The hospital in which the cardiac catheterization laboratory is located has verified and documented that the registered cardiovascular invasive specialist has completed the training and education and has the experience required by regulations adopted by the Board.

(2) The hospital in which the cardiac catheterization laboratory is located and the physician delegating duties to a registered cardiovascular invasive specialist under this subsection are responsible for ensuring that all requirements of this subsection are met for each procedure.

(3) A disciplinary panel may impose a civil penalty of up to $5,000 for each instance of a hospital's failure to comply with the requirements of this subsection.

§14–306. ** TAKES EFFECT SEPTEMBER 30, 2024 PER CHAPTER 445 OF 2019 **

(a) To the extent permitted by the rules, regulations, and orders of the Board, an individual to whom duties are delegated by a licensed physician may perform those duties without a license as provided in this section.

(b) The individuals to whom duties may be delegated under this section include any individual authorized to practice any other health occupation regulated under this article or § 13–516 of the Education Article.

(c) The Board shall adopt rules and regulations to delineate the scope of this section. Before it adopts any rule or regulation under this section, the Board shall invite and consider proposals from any individual or health group that could be affected by the rule or regulation.

(d) (1) If a duty that is to be delegated under this section is a part of the practice of a health occupation that is regulated under this article by another board, any rule or regulation concerning that duty shall be adopted jointly by the Board of Physicians and the board that regulates the other health occupation.

(2) If the two boards cannot agree on a proposed rule or regulation, the proposal shall be submitted to the Secretary for a final decision.

(e) Except as otherwise provided in this section, an individual may perform X–ray duties without a license only if the duties:

(1) Do not include:

(i) Computerized or noncomputerized tomography;

(ii) Fluoroscopy;

(iii) Invasive radiology;

(iv) Mammography;

(v) Nuclear medicine;

(vi) Radiation therapy; or

(vii) Xerography;

(2) Are limited to X–ray procedures of the:

(i) Chest, anterior–posterior and lateral;

(ii) Spine, anterior–posterior and lateral; or

(iii) Extremities, anterior–posterior and lateral, not including the head; and

(3) Are performed:

(i) By an individual who is not employed primarily to perform X–ray duties;

(ii) In the medical office of the physician who delegates the duties; and

(iii) 1. By an individual who, before October 1, 2002, has:

A. Taken a course consisting of at least 30 hours of training in performing X–ray procedures approved by the Maryland Radiological Society in consultation with the Maryland Society of Radiologic Technologists; and

B. Successfully passed an examination based on that course that has been approved by the Maryland Radiological Society in consultation with the Maryland Society of Radiologic Technologists; or

2. By a licensed physician assistant who has completed a course that includes anterior–posterior and lateral radiographic studies of extremities on at least 20 separate patients under the direct supervision of the delegating physician or radiologist using a mini C–arm or similar low–level radiation machine to perform nonfluoroscopic X–ray procedures, if the duties:

A. Include only the X–ray procedures described in paragraph (2)(iii) of this subsection; and

B. Are performed pursuant to a Board–approved delegation agreement that includes a request to perform advanced duties under § 15–302(c)(2) of this article.

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VOL. 39/NO. 1 SPRING 2024

GORDON·FEINBLATT LLC
ATTORNEYS AT LAW

Topics

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

Narrowing the Definition of an Illegal Kickback

In the Spring of 2023, the Sixth Circuit, which is the federal appellate court with jurisdiction for Kentucky, Michigan, Ohio and Tennessee, issued an unprecedented opinion in *Martin v. Hathaway*, holding for the first time by a federal appellate court that "remuneration" in the federal Anti-Kickback Statute (AKS) means "just payments and other transfers of value" and not "any act that may be valuable to another."

Additionally, the Sixth Circuit joined the Eighth Circuit, the federal appellate court with jurisdiction for Arkansas, Iowa, Minnesota, Missouri, Nebraska, North Dakota and South Dakota, in determining that reliance on a violation of the AKS to find a violation of the False Claims Act (FCA) requires a showing of "but-for" causation, deepening a split with the Third Circuit, the federal appellate court with jurisdiction for Pennsylvania, New Jersey, Delaware and the U.S. Virgin Islands, on what connection is required between a kickback and a subsequent reimbursement claim.

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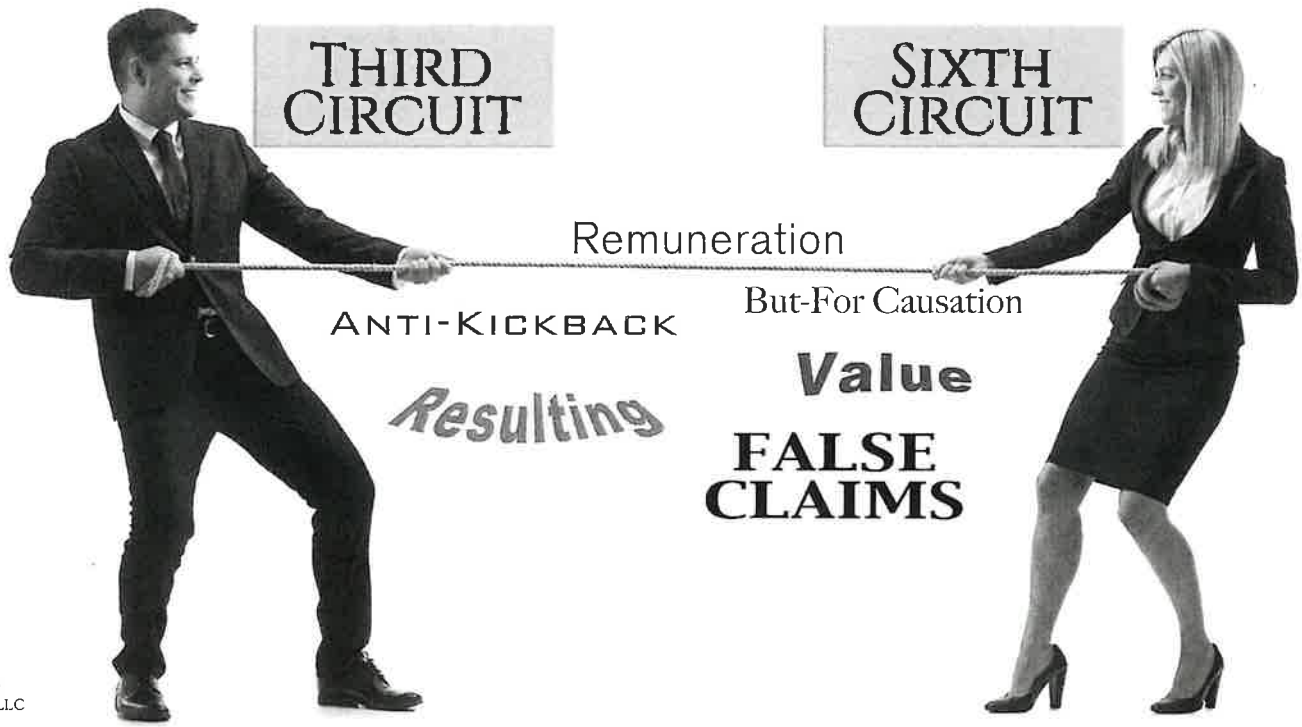

A. The Facts of the Case

In *Martin v. Hathaway*, Dr. Martin, an ophthalmologist sued her former employer, Dr. Hathaway, the owner of an ophthalmology practice, and Oaklawn, the local hospital, under the federal and state False Claims Acts. Dr. Martin alleged that Dr. Hathaway and Oaklawn engaged in an illegal fraudulent scheme under the AKS.

The alleged scheme involved Dr. Hathaway interfering with Oaklawn hiring Dr. Martin by informing Oaklawn that the hiring would force Dr. Hathaway to refer his patients to a different hospital where he could perform surgical procedures instead of referring to Oaklawn where Dr. Martin would be on staff to perform the procedures for the hospital, cutting into Dr. Hathaway's revenue stream.

B. Remuneration

The AKS prohibits payment or receipt of "remuneration" in exchange for referrals of patients to receive services paid for by federal or state health care programs. The Sixth Circuit determined that Oaklawn's refusal to hire Dr. Martin in return for Dr. Hathaway's continued surgical referrals was not "remuneration" under the AKS.

The term "remuneration" is not defined in the AKS. Instead, the Sixth Circuit looked to the dictionary definitions of "remuneration," other federal law definitions of "remuneration," the U.S. Health and Human Services' Office of the Inspector General opinions and the general theme of the AKS safe harbors to determine that "remuneration" requires a transfer of payment or value.

The court determined that Oaklawn's decision not to hire Dr. Martin was too attenuated from the referrals made by Dr. Hathaway to Oaklawn to find that the decision could be "remuneration." The court pointed to the fact that there wasn't any agreement in place between Oaklawn and Dr. Hathaway, no requirement for a specific volume of referrals, and no time frame for the agreement to take place. Additionally, the court argued that because the AKS creates both civil and criminal liability, a narrower definition of "remuneration" is appropriate where the statutory language is ambiguous.

C. Causation

The FCA imposes civil liability for knowingly submitting a false or fraudulent claim to the government for payment. The AKS prohibits payment or receipt of "remuneration" in exchange for referrals of patients to receive services paid for by federal or state health care programs. Any claims "resulting from" an AKS violation, which is a criminal statute, are considered false claims for purposes of the FCA.

To find a violation of the FCA in reliance on a violation of the AKS, a court must determine that the claims at issue "resulted from" the illegal "remuneration" under the AKS. Relying on the 2014 Supreme Court decision in *Burrage v. United States*, the Sixth Circuit in *Martin v. Hathaway* determined that the ordinary meaning of "resulting from" is but-for causation, meaning that the referral would not have occurred "but-for" Oaklawn's refusal to hire Dr. Martin.

The Sixth Circuit determined that Dr. Martin had not alleged the required causation because the decision by Oaklawn not to hire Dr. Martin, allegedly to maintain a referral source in Dr. Hathaway, did not change anything in the referral relationship between Oaklawn and Dr. Hathaway. Therefore, the decision did not cause the referrals.

The Sixth Circuit joins the Eighth Circuit in determining that "but-for" causation is the appropriate standard in these cases. In opposition, the Third Circuit in 2018, held that some connection is required between the illegal kickback and the submission of a claim, but it is not necessary to prove that the claim would not have occurred without the kickback. The

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Third Circuit reasoned that health care fraud is often difficult to prove and a more lenient interpretation would increase the challenges in FCA enforcement cases based on the AKS.

D. Conclusion

The Sixth Circuit in *Martin v. Hathaway* provides an opportunity for other circuits to adopt the narrower definition of "remuneration" and join the circuit split on the required causation to find an FCA violation under the AKS, making it more difficult for the government and individual complainants to bring successful AKS and FCA cases against providers.

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LLC Operating Agreements

This is the third part of a several part series of articles pertaining to limited liability company operating agreements. This third installment addresses capital calls, covenants not to compete and fiduciary duties.

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. Capital Calls

Capital calls refer to the ability of the LLC to request additional capital contributions from its members. Typically, they may be used to fund shortfalls during lean years, or to provide capital for projects that are outside of the scope of a projected budget. Many businesses use capital calls when they are unwilling or unable to obtain traditional financing.

When a capital call is made, the funds are attributed to the member's capital accounts as additional investments in the business.

LLC operating agreements should address how and when a capital call can be made, if at all, and address the length of any notice period.

The operating agreement should also provide guidelines on how to address a failure to meet the call. For instance, if a member refuses to participate, the participating members could dilute the non-participating member's ownership interest.

Let's take for example a three member LLC, where each member has an equal 33.33% interest in the company having initially contributed $10,000 each. Presume that a capital call is made for $30,000, and each member is asked to contribute an additional $10,000. One member refuses to participate, but the other two members make up the shortfall and each contribute $15,000.

If the company has distributed all of its profits and has not incurred any losses, then after the new $30,000 capital call, the participating members will each have $25,000 in their capital accounts, and the non-participating member will have $10,000 in their capital account. Under a standard dilution scenario, the non-participating member's ownership interest would be reduced from 33.33% to 16.67%, and the participating members would now each have a 41.67% interest.

Alternatively, the operating agreement in the above example could allow for the participating members' $15,000 contributions to be treated as a loan to the company, and not as added capital.

B. Covenants Not to Compete

Covenants not to compete are important in operating agreements for several reasons, particularly in industries such as health care where the protection of patient relationships and business goodwill is paramount. These covenants prevent members from engaging in competing activities during the term of their membership, and sometimes for a period after termination of their interest.

Covenants not to compete can also help ensure that departing members do not use confidential information, such as patient lists or business strategies, to compete with the company. There may also be non-solicitation language that prevents departing members from soliciting patients or poaching employees of the LLC.

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The LLC operating agreement language should be tailored appropriately such that the restrictions are reasonable in duration and geography; otherwise, the provisions may be unenforceable. As with other covenants not to compete, there may be different terms in the event a member leaves the business voluntarily or involuntarily.

It is important to note that covenants not to compete in operating agreements can generally be broader in scope than similar provisions in employment agreements. Courts generally believe that owners of businesses pose a greater threat to a business, and are more capable of finding alternative employment, than a departing employee.

C. Fiduciary Duties

Fiduciary duties are crucial in operating agreements because they establish the standards of conduct for LLC members, including their acting in the best interests of the LLC and its members. Fiduciary duties also include the duty of loyalty and the duty of care, protecting the LLC and its members from misconduct or self-serving actions by other members.

Members should be required to treat each other and the company fairly and honestly, and maintain a culture of transparency and accountability. Members should be expected to act in the best interests of the LLC and its members, and not for their own personal interests.

This includes disclosure of conflicts of interest by members, and oftentimes require members to provide the company with information and time for consideration of opportunities before a member can act on the opportunity personally.

Of note, while many states impose fiduciary duties for limited liability companies by statute, Maryland does not. However, in 2020, Maryland's highest appellate court ruled that fiduciary duties exist as to majority members' actions towards minority members of an LLC in the case *Plank v. Cherneski*. Given the importance of fiduciary duties to protecting the company as well as the other members, it is advisable to include specific provisions regarding fiduciary duties in an LLC's operating agreement.

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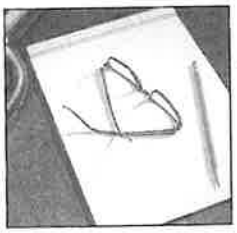

Maryland Regulatory News

1. In January 2024, the Maryland Department of Health and Health Services Cost Review Commission initiated advisory committee meetings to discuss the State's application to the Center for Medicare and Medicaid Innovation's Advancing All-Payer Health Equity Approaches and Development (AHEAD) Model. AHEAD is a new model available to a small cohort of states that will include elements similar to Maryland's Total Cost of Care Model and the Maryland Primary Care Program. The AHEAD Model is scheduled to begin in January 2026, and will pick up just as Maryland's current waiver programs end at the end of 2025.

2. The Maryland Health Care Commission on February 22, 2024, adopted the regulations proposed in October 2023 which amended the Certificate of Need regulations. No comments were submitted during the thirty day comment period.

3. Maryland Medicaid expanded coverage for gender-affirming care, effective January 1, 2024. New covered services include hormone therapy and lab testing, voice surgery, therapy and lessons, hair removal and transplants, gender affirming surgery and other related services. This expansion follows the enactment of the Trans Health Equity Act in Maryland.

4. In January 2024, the Maryland Department of Labor circulated draft regulations to implement the Family and Medical Leave Insurance Program (also known as the Maryland Time to Care Act). These regulations are not officially proposed but are instead being used to solicit comments and feedback to the Department. The Maryland General Assembly is also considering further amendments to the Act. Employers will be required to contribute to the state fund beginning in Fall 2024, unless the employer secures alternative coverage for the required benefits. The benefits are scheduled to become available to covered employees in 2026.

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Medicare Drug Price Negotiations

In 2022, the United States Congress passed the Inflation Reduction Act (IRA) which gave Medicare the authority to negotiate certain prescription drug prices with manufacturers for the first time. The intent of this law is to reduce the cost of some of the most expensive drugs and increase access to patients through Medicare Part B and D.

A. Annual Cycles

In August 2023, the Centers for Medicare and Medicaid Services (CMS) announced the first 10 drugs that it selected for negotiation. All of these drugs are covered under Medicare Part D. CMS selected these drugs based on total expenditures under Part D and other criteria as required by the IRA. The negotiations will occur through 2024, and the rate will become effective beginning in 2026.

In early 2024, CMS will send an initial offer for each selected drug to the participating drug company. The drug company has 30 days to respond by accepting or providing a counteroffer. If an agreement is not reached in the initial offer and counteroffer, CMS will invite the drug company to up to three negotiation meetings in the Spring and Summer of 2024.

The negotiation period will end on August 1, 2024. By that date, the drug companies are expected either to accept a negotiated rate, reject the negotiated rate and pay an excise tax on sales of the selected drug to Medicare during defined periods, or remove its drug from the Medicare and Medicaid programs.

CMS will publish any agreed to rates by September 1, 2024, and those rates will be effective for the Medicare program as of January 1, 2026.

CMS will continue this negotiation program for additional cycles adding 15 more drugs in both 2027 and 2028 (which will also include Part B drugs), and 20 drugs in each year after that.

B. Lawsuits

Nine lawsuits have been filed against the U.S. Department of Health and Human Services and CMS, mainly by pharmaceutical companies impacted by the negotiation program, arguing that the program is unconstitutional. The companies believe that the program will financially harm them and stifle innovation required to develop life-saving drugs.

In the fall of 2023, one court denied the pharmaceutical companies' request for a preliminary injunction against the negotiation program, allowing the program to proceed while the cases pend in court.

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No Surprises Act– A New and Improved Proposed Rule

The No Surprises Act (NSA), effective January 1, 2022, generally protects patients from receiving unanticipated bills for emergency care rendered by providers who do not participate with the patient's insurance coverage (out-of-network providers), and includes a prohibition on certain out-of-network providers balance billing patients.

The law also requires that the patient's insurer reimburse the out-of-network provider the rate provided either by a state All-Payer Model Agreement (such as Maryland's All-Payer Model), other state law that sets the reimbursement rate for the service, or in the absence of both of those, an amount (1) agreed to by the insurer and the out-of-network provider or (2) determined through an independent dispute resolution (IDR) process.

A. Judicial Intervention

In August 2023, two court orders were issued once again halting the IDR process by vacating certain portions of the out-of-network billing regulations, focusing on the calculation of the "qualifying payment amount" used to set-

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tle disputes between providers and insurance companies over the amount owed to providers.

B. The New Rule

As a result, in October 2023, the Centers for Medicare and Medicaid Services released new proposed rules for the dispute resolution process that contain the following elements:

1. Payers must include additional information with their initial payments or denials, such as the qualifying payment amount and contact information for initiating the open negotiation period.

2. The provider must provide an open negotiation notice to the payer and the Department through the federal IDR portal to initiate the open negotiation period, which will start the open negotiation period of 30 days.

3. The receiving party must file an open negotiation response notice to the other party and the Department by the 15th business day of the open negotiation period.

4. Increased flexibility to "batch" claims into one dispute for settlement.

5. Eligibility determinations by IDR entities must be done within five business days.

Noticeably absent are the previously objected to elements that directed the IDR entities in how to weigh the information submitted when making a determination regarding the reimbursement rate.

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New OIG Compliance Guidelines

In the first major update in fifteen years, the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) recently released new voluntary compliance program guidelines (CPGs) for health care companies aimed at preventing fraud and waste in the health care system.

Last spring, the OIG announced plans to update and to release new CPGs, recognizing that technology and which entities are involved in health care have vastly changed health care delivery.

The first new CPG is a general CPG, offering a concise overview of compliance expectations for all providers. The OIG plans to release additional guidance for subcategories of providers, such as nursing facilities, later this year.

A. Overview

While CPGs are not binding, the documents provide useful insight into relevant federal laws, illustrative examples of common issues and references to other OIG resources that might be helpful for companies as they proactively shape their compliance programs and address issues as they arise.

Further, the OIG recognizes that compliance efforts cannot be "one size fits all" given the range of entities involved in health care, and offers suggestions for both large and small companies to consider to create effective programs to meet their compliance obligations given their relative access to resources.

The guide contains summaries of relevant laws, such as the Anti-Kickback Statute (AKS), Physician Self-Referral Law, known as the Stark Law, the False Claims Act, and the Health Insurance Portability and Accountability Act (HIPAA), among others.

It also reiterates in detail the key elements of a compliance program, ranging from having written policies and procedures, training and education plans, and conducting risk assessments at least annually, among other components.

B. Recent Trends

While much of the guidance will be familiar to seasoned compliance professionals, the CPG does capture many recent trends in the health care industry.

For example, in alignment with other federal efforts, the CPG explicitly states that quality and patient safety measures should be included as part of compliance efforts, and compliance materials should be accessible and inclusive of the diverse array of professionals in health care today, including publishing materials in different languages as applicable, and finding new ways to communicate with employees of different generations who may have different communication styles.

Additionally, the OIG flags that over the last two decades, many new players, including private equity, technology companies and care coordination service providers, have entered the health care sphere, and even traditional entities have expanded into new services. The OIG stresses that investors and compliance officers should revise and tailor their efforts to these new offerings and relationships to avoid running afoul of federal requirements.

With more guidance on the way, owners, providers and other interested parties should take this opportunity to review their compliance programs as the landscape continues to evolve.

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Did You Know?

340B Program: Did you know that hospitals and other covered entities may have more access to discounted drugs under the 340B program? A recent federal district court decision held that the interpretation of the word patient in the 340B program by the Health Resources and Services Administration (HRSA), which required that a covered entity must initiate the service resulting in the discounted prescription, was narrower than Congress intended. Instead, any patient with an "ongoing relationship" with a covered entity would suffice, meaning more outpatient drug purchases may be eligible for discounts. This decision also complicates the ongoing dispute over the future of the 340B program, driven by pharmaceutical companies who seek to limit available discounts and covered entities who have come to depend on the savings the program provides, since it is now unclear the extent to which HRSA can enforce or prevent restrictions favored by either industry without action from Congress.

Health Data: Did you know that the Office of the National Coordinator for Health Information Technology published a final rule in January 2024, regarding health data, technology, and interoperability. The final rule establishes new transparency and risk management requirements for the use of artificial intelligence (AI) and algorithms used in certified information technology. These new requirements will be important to developers of health IT modules, and go into effect starting January 1, 2025.

Tracking Technologies: Did you know that a number of hospital associations and health systems, including the American Hospital Association, have sued the Department of Health and Human Services Office of Civil Rights (OCR) in regard to its December 2022 tracking technologies bulletin? The OCR bulletin concluded that tracking technologies embedded in most websites are potentially being used in violation of the Health Insurance Portability and Accountability Act (HIPAA). The parties initiating the lawsuit argue that the OCR's bulletin amounts to a new regulation, and should have followed the required notice and comment period. Those parties further argue that removing this tracking data will remove web tools that are essential, including video technologies, translation and accessibility services, and digital maps about where services can be accessed by patients. The case is still pending in a Texas district court.

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Doctors Unionizing

In March 2023, approximately 100 physicians at a Minneapolis hospital owned by Allina Health voted to unionize. Just seven months later, over 400 primary care physicians employed in clinics owned by the same health system also voted to join the Doctors Council of the Service Employees International Union.

This recent push to unionize is likely being fueled by the consolidation of health care companies and health systems, which are employing more and more doctors, combined with the strain of the pandemic.

Some mistakenly believe that unionization is not available to doctors because the National Labor Relations Act (NLRA) does not apply to supervisors, meaning generally individuals who have the power to hire, fire and direct other employees.

However, the National Labor Relations Board (NLRB), as recently as 2022, in the *Piedmont Health Services* case, concluded that physicians, nurse practitioners, certified nurse-midwives and physician assistants may not be supervisors under the NLRA. Due to the management and operational structure of the employer, the NLRB found that the physicians did not routinely direct other employees, assign work or engage in personnel decisions, but their primary role was the provision of health care services to patients.

Some doctors question union membership for many reasons. For example, some disfavor the concept because collective bargaining agreements rarely reward high performers. Others express concerns about striking, since strikes can, of course, negatively impact patient care and health outcomes.

In any case, presently about eight percent of practicing physicians in the United States are union members, and it will be interesting to see if that percentage does or does not grow in the coming years.

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Coming in Future Issues

- **Operating Agreements**
- **Part II Regulations**
- **New Maryland Legislation**