

**Maryland General Assembly  
Department of Legislative Services**

**Proposed Regulations  
Department of Health and Mental Hygiene  
(DLS Control No. 15-284)**

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**Overview and Legal and Fiscal Impact**

The regulations expand the Drug Therapy Management Program to authorize licensed podiatrists and certified advance practice nurses with prescriptive authority, rather than only physicians, to enter into a therapy management contract.

The regulations present no legal issues of concern.

There is no fiscal impact on State or local agencies beyond that already assumed under the fiscal and policy note for Chapter 269 of 2015.

**Regulations of COMAR Affected**

**Department of Health and Mental Hygiene:**

Board of Pharmacy: Drug Therapy Management: COMAR 10.34.29.01-.07

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**Legal Analysis**

**Background**

Chapter 249 of 2002 established the Drug Therapy Management Program, which authorizes a physician and a pharmacist to enter into a therapy management contract that specifies treatment protocols that may be used to provide care to a patient. Chapter 269 of 2015 expanded the program to authorize licensed podiatrists and certified advance practice nurses with prescriptive authority, rather than only licensed physicians, to enter into a therapy management contract. Chapter 269 also renamed the “physician-pharmacist agreement” to be the “prescriber-pharmacist agreement”, accordingly.

**Summary of Regulations**

The regulations implement the statutory changes enacted under Chapter 269 of 2015. These include: defining “authorized prescriber” to include a licensed physician, podiatrist, or certified advance practice nurse with prescriptive authority; making corresponding changes throughout the chapter relating to the expanded definition of “authorized prescriber”; referencing the Health Occupations Board that regulates the authorized prescriber, where appropriate; renaming the “physician-pharmacist agreement” to be the “prescriber-pharmacist agreement”; allowing a protocol between a licensed physician and a licensed pharmacist to authorize the

initiation of drug therapy under written, disease-state specific protocols; and repealing the requirement for a therapy management contract to terminate one year from the date of signing, unless renewed.

### **Legal Issues**

The regulations present no legal issues of concern.

### **Statutory Authority and Legislative Intent**

The Department of Health and Mental Hygiene cites §§ 12-6A-01, 12-6A-03 through 12-6A-08, and 12-6A-10 of the Health Occupations Article as statutory authority for the regulations. Section 12-6A-01 defines terms relating to therapy management contracts including “authorized prescriber”. Sections 12-6A-03 through 12-6A-08 set forth the requirements, composition, contents, and procedure for termination of prescriber-pharmacist agreements as well as the substance of protocols established under the program. Section 12-6A-10 requires the board, together with the State Board of Physicians and in consultation with the State Board of Podiatric Medical Examiners and the State Board of Nursing, to develop and adopt regulations relating to the program.

This authority is correct and complete. The regulations comply with the legislative intent of the law.

### **Technical Corrections**

The State Board of Pharmacy has submitted replacement pages to the Division of State Documents that would correct references to an “authorized prescriber” rather than to a “physician”.

### **Fiscal Analysis**

There is no fiscal impact on State or local agencies beyond that already assumed under the fiscal and policy note for Chapter 269 of 2015.

### **Agency Estimate of Projected Fiscal Impact**

The regulations implement Chapter 269 of 2015 (House Bill 716), which expanded the Drug Therapy Management Program to include additional authorized prescribers (licensed podiatrists and certified advanced practice nurses with prescriptive authority) rather than only licensed physicians. The Act also specified that protocols by a licensed physician and a licensed pharmacist may authorize the initiation of drug therapy under written, disease-state specific protocols. The board advises that the regulations have an indeterminable fiscal and operational impact on the board. The Department of Legislative Services disagrees and notes that any potential fiscal and operational impact has already been assumed in the fiscal and policy note for House Bill 716 of 2015.

The fiscal and policy note for House Bill 716 noted that pharmacists currently pay a \$100 fee to the board to submit a physician-pharmacist agreement. To the extent the number of prescriber-pharmacist agreements increases due to expanding the program to licensed podiatrists and certified advanced practice nurses with prescriptive authority, special fund revenues for the board increase by a minimal amount beginning in fiscal 2016, with no anticipated impact on expenditures.

### **Impact on Budget**

There is no impact on the State operating or capital budget beyond that already assumed in the fiscal and policy note for House Bill 716 of 2015.

### **Agency Estimate of Projected Small Business Impact**

The board advises that the regulations have minimal or no economic impact on small businesses in the State. The Department of Legislative Services concurs.

### **Contact Information**

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