

**Maryland General Assembly
Department of Legislative Services**

**Proposed Regulation
Department of Health and Mental Hygiene
(DLS Control No. 14-130)**

Overview and Legal and Fiscal Impact

The regulation alters the number, composition, and terms of members serving on the Maryland AIDS Drug Assistance Program Advisory Board.

The regulation presents no legal issue of concern.

There is no fiscal impact on State or local agencies.

Regulation of COMAR Affected

Department of Health and Mental Hygiene:

Human Immunodeficiency Virus (HIV) Infection and Acquired Immunodeficiency Syndrome (AIDS): Maryland AIDS Drug Assistance Program: Services:
COMAR 10.18.06.04-2

Legal Analysis

Background

The Maryland AIDS Drug Assistance Program (MADAP) gives people living with HIV/AIDS in Maryland access to the medication they need to stay healthy. Funded primarily through the federal Ryan White Act, MADAP pays for medications for eligible clients with no insurance and helps clients with insurance by paying for eligible co-pay and deductible costs so they can get their medication. The list of medicines covered by MADAP includes a wide range of medications used to treat HIV infection, opportunistic infections, and complications of HIV infection or related conditions, including all anti-retroviral therapies approved by the U.S. Food and Drug Administration. Individuals enrolled in MADAP can use MADAP to receive their medications at any of the approximately 1,100 pharmacies that accept Maryland Medical Assistance.

To qualify for MADAP services, an individual must:

- be diagnosed as having HIV;
- qualify financially (anticipated gross annual household income must be at or below 500% of the federal poverty level for the size of the legal household);

- be a resident of Maryland;
- not be eligible for Medicaid or Primary Adult Care; and
- submit a complete application with required documentation.

The MADAP-Plus program helps people living with HIV/AIDS in Maryland access medications by obtaining or maintaining health insurance. Also funded primarily by the federal Ryan White Act, MADAP-Plus pays premiums for health insurance plans with prescription coverage (or prescription plans) for eligible individuals. To qualify for MADAP-Plus, an individual must be eligible for MADAP, be responsible for paying 50% or more of their health insurance premium, and have completed the insurance section of the MADAP combined application, with required documentation.

The MADAP Advisory Board is established in regulation for the purpose of developing recommendations for the MADAP formulary. Prior to 2014, the number and composition of board members were not specified in the regulations. Under emergency regulations effective January 1, 2014, the board:

- consists of a maximum of 11 members, including up to seven clinician members and up to four community members, all of whom are appointed by the Secretary of Health and Mental Hygiene;
- must meet at least twice per year, instead of quarterly; and
- in developing recommendations for the MADAP formulary, must consider the availability of other drugs on the MADAP formulary to treat the same condition.

Summary of Regulation

The regulation increases the membership of the board from a maximum of 11 to a maximum of 18 members. The number of clinician members is increased to nine from up to seven, and registered nurses are included as potential clinician members. The number of community representative members is increased to nine from up to four, and MADAP consumers replace individuals living with HIV as potential community representative members.

Additionally, the regulation alters the length of the term of board members from two years to three years and allows members to serve two consecutive terms without being off the board for a year. Under the regulation, the terms of the board members serving on December 31, 2014 expire on January 1, 2015. Terms of the initial board members are staggered over one to three years, with the staggered terms assigned through a drawing.

Legal Issue

The regulation presents no legal issue of concern.

Statutory Authority and Legislative Intent

MADAP has no specific statutory authority. The Department of Health and Mental Hygiene cites §§ 2-104(b) and (i), 2-105(a) and (b), and 18-102 of the Health – General Article as authority for the regulations. Section 2-104(b) authorizes the Secretary to adopt rules and regulations to carry out the provisions of law that are within the jurisdiction of the Secretary. Section 2-104(i) authorizes the Secretary to apply for, receive, and spend federal funds to carry out the powers and duties of the Secretary or the department. Section 2-105(a) requires the Secretary to establish general policy for and adopt standards to promote and guide the development of, the physical and mental hygiene services of the State and its subdivisions. Section 2-105(b) makes the Secretary responsible for the health interests of the people of the State and requires the Secretary to supervise generally the administration of the health laws of the State and its subdivisions. Section 18-102 requires the Secretary to adopt rules and regulations and take specified actions necessary to prevent the introduction or spread of an infectious or contagious disease into the State or other disease that endangers public health.

The regulation complies with legislative intent.

Special Notes

The Statement of Purpose for the regulation is not accurate. It says that the purpose is to “clarify the Maryland AIDS Drug Assistance Program Advisory Board member selection process and term limits”. In fact, the regulation *alters* the number, composition, and terms of members. (Emphasis added.)

Fiscal Analysis

There is no fiscal impact on State or local agencies.

Agency Estimate of Projected Fiscal Impact

The regulation alters the maximum number, composition, and terms of members serving on the Maryland AIDS Drug Assistance Program Advisory Board. The department advises that the regulations have no fiscal impact. The Department of Legislative Services concurs and notes that altering the appointment process and terms of board members does not affect governmental finances.

Impact on Budget

There is no impact on the State operating or capital budget.

Agency Estimate of Projected Small Business Impact

The department advises that the regulation has minimal or no economic impact on small businesses in the State. The Department of Legislative Services concurs.

Contact Information

Legal Analysis: Linda L. Stahr – (410) 946/(301) 970-5350

Fiscal Analysis: Kathleen P. Kennedy – (410) 946/(301) 970-5510