

**Maryland General Assembly
Department of Legislative Services**

**Proposed Regulations
Department of Health and Mental Hygiene
(DLS Control No. 16-139)**

Overview and Legal and Fiscal Impact

The regulations conform requirements under the Maryland Medical Assistance Program for preauthorization of specified physician, pharmacy, hospital, and medical laboratory services relating to gender reassignment with the Maryland State Employees' Health Benefit program and recent changes in Medicare policy.

The regulations present no legal issues of concern.

There is no fiscal impact on State or local agencies.

Regulations of COMAR Affected

Department of Health and Mental Hygiene:

Medical Care Programs: Physicians' Services: COMAR 10.09.02.06

Pharmacy Services: COMAR 10.09.03.06

Hospital Services: COMAR 10.09.06.06

Medical Laboratories: COMAR 10.09.09.05

Legal Analysis

Background

In a May 30, 2014 decision, the United States Department of Health and Human Services Departmental Appeals Board determined that the National Coverage Determination (NCD) denying Medicare coverage of all transsexual surgery as a treatment for transsexualism was no longer valid under the "reasonableness standard" applied by the board. The board explained that the NCD was based on information gathered in 1981. The record for the May, 2014 decision included expert medical testimony and studies published after the NCD. The board explained that because "the NCD is no longer valid, its provisions are no longer a valid basis for denying claims for Medicare coverage of transsexual surgery, and local coverage determinations used to adjudicate such claims may not rely on the provisions of the NCD. The decision does not bar Centers for Medicare and Medicaid Services or its contractors from denying individual claims for payment for transsexual surgery for other reasons permitted by law."

Summary of Regulations

The regulations alter the preauthorization requirements for physicians' services by adding a requirement for preauthorization of surgical procedures for the purpose of gender reassignment.

The regulations repeal the requirement for a provider to obtain preauthorization from the Department of Health and Mental Hygiene for a prescription related to gender dysphoria. A provider is required to obtain preauthorization from the department for female hormones for biologic males when used for treating sexual aggression.

The regulations alter the preauthorization requirements for hospital services by requiring preauthorization for all inpatient evaluations, procedures, and treatments related to gender reassignment.

The regulations repeal obsolete language that prohibited the coverage of medical laboratory services associated with sex change because medical laboratory services associated with gender reassignment are currently covered due to changes in Medicare policy.

Legal Issues

The regulations present no legal issues of concern.

Statutory Authority and Legislative Intent

The Department of Health and Mental Hygiene cites §§ 2-104(b), 15-102.8, 15-103, 15-103.1, 15-105, and 15-118 of the Health – General Article as statutory authority for the regulations. Section 2-104(b) authorizes the Secretary of Health and Mental Hygiene to adopt regulations to carry out the provisions of law that are within the jurisdiction of the Secretary. Section 15-102.8 authorizes the department to impose a claims processing charge on all Medicaid claims processed, approved, and paid by the department to hospitals located in the District of Columbia for the provision of inpatient and outpatient services. Section 15-103 requires the Secretary to administer the Maryland Medical Assistance Program. Section 15-103.1 requires the program to use its leverage as a high volume purchaser to promote the cost effectiveness of Maryland's health care system. Section 15-105 requires the department to adopt regulations for the reimbursement of providers under the program. Section 15-107 authorizes the Secretary to establish appeal boards and to designate the jurisdiction of a board to hear an appeal of a facility concerning the results of a field verification of the costs and allowable charges of a facility that participates in the program.

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

Fiscal Analysis

There is no fiscal impact on State or local agencies.

Agency Estimate of Projected Fiscal Impact

The regulations align Medicaid coverage of gender reassignment surgery with the State Employee and Retiree Health and Welfare Benefit Program and recent changes in Medicare policy. As gender reassignment is already covered under Medicaid, the department advises that the regulations have no impact on State or local governments. The Department of Legislative Services concurs.

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

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