

**Maryland General Assembly  
Department of Legislative Services**

**Proposed Regulations  
Department of Health and Mental Hygiene  
(DLS Control No. 15-001)**

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## **Overview and Legal and Fiscal Impact**

The regulations require kidney dialysis facilities to have an emergency plan, require the director of a renal transplantation center to be a physician who meets specified requirements, require freestanding dialysis facilities to comply with a quality assurance program, authorize a nurse practitioner to be a monitoring individual, and establish standards for kidney dialysis facilities that perform nocturnal hemodialysis.

The regulations present no legal issue of concern.

There is no fiscal impact on State or local agencies.

## **Regulations of COMAR Affected**

### **Department of Health and Mental Hygiene:**

Commission on Kidney Disease: General Regulations:

COMAR 10.30.01.02, .03, and .11

Physical and Medical Standards: COMAR 10.30.02.02-.07

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## **Legal Analysis**

### **Background**

The Department of Health and Mental Hygiene states that the Commission on Kidney Disease is aligning its regulations with those of the Office of Health Care Quality, with which dialysis facilities should already be in compliance.

### **Summary of Regulations**

The regulations require a kidney dialysis facility to have an emergency plan, which must include specified policies and procedures that will be followed before, during, and after an emergency. The facility shall provide access to the emergency plan to local organizations for emergency management. The regulations also establish requirements for generators and their use during an emergency.

The regulations require the director of a renal transplantation center to be a physician who meets specified requirements.

The regulations require freestanding dialysis facilities to comply with a quality assurance program and to provide specified documentation of the program. A nurse practitioner is authorized to be a monitoring individual in a freestanding dialysis facility.

The regulations authorize nocturnal hemodialysis to be provided in kidney dialysis facilities. The regulations establish standards for nocturnal hemodialysis programs in freestanding dialysis facilities, including nephrologist or physician qualifications, responsibilities of the medical director, nurse manager and charge nurse qualifications, staffing ratio and requirements for the monitoring individual, and responsibilities of the social worker.

## **Legal Issue**

The regulations present no legal issue of concern.

## **Statutory Authority and Legislative Intent**

The department cites §§ 13-301 through 13-316 and 16-204 of the Health – General Article as legal authority for the proposed regulations. More specifically, the regulations are authorized by § 13-308 of the Health – General Article.

Section 13-308(a) authorizes the commission to adopt regulations to carry out the provisions of law relating to the Kidney Disease Program in the department. Section 13-308(b) requires the commission to adopt physical and medical standards for the operation of dialysis and transplant centers.

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 establish standards for kidney dialysis facilities that perform nocturnal hemodialysis, alter staffing requirements at transplant centers, require freestanding dialysis facilities to comply with a certain quality assurance program, authorize a nurse practitioner to serve as a monitoring individual in a freestanding dialysis facility, and incorporate requirements regarding emergency management. The department advises that these changes reflect either current requirements imposed on dialysis facilities by the federal Centers for Medicare and Medicaid Services or mirror existing Office of Health Care Quality regulations governing dialysis facilities. Therefore, there is no fiscal impact. 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.

### **Contact Information**

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