

Department of Legislative Services
Maryland General Assembly
2014 Session

FISCAL AND POLICY NOTE

House Bill 1555 (Delegate Bromwell)
Health and Government Operations

Health Occupations - Maryland Perfusion Act - Applicability

This bill exempts, from the requirement to be licensed as a perfusionist by the State Board of Physicians (MBP), (1) a person who preserves human organs for transplantation under an investigational device exemption clinical trial or a humanitarian device exemption approved by the U.S. Food and Drug Administration (FDA) or (2) a federally designated organ procurement organization.

The bill takes effect July 1, 2014.

Fiscal Summary

State Effect: The bill does not materially affect State finances.

Local Effect: None.

Small Business Effect: Meaningful for any small businesses that may employ individuals exempt from the licensure requirement under the bill.

Analysis

Current Law: Chapter 588 of 2011 (the Maryland Perfusion Act) required MBP to license and regulate the practice of perfusion and established a Perfusion Advisory Committee (PAC) within MBP. Under Chapter 588, on or after October 1, 2013, an individual must be licensed to practice perfusion in Maryland. Only students enrolled in an accredited perfusion education program are exempt from this requirement.

Per § 14-5E-01(f) of the Health Occupations Article, “practice perfusion” means to perform the functions necessary for the support, treatment, measurement, or supplementation of the cardiovascular, circulatory, or respiratory systems or other organs to ensure the safe management of physiologic functions by monitoring and analyzing the parameters of the systems under an order and the supervision of a licensed physician. “Practice perfusion” includes 30 specific procedures, including organ procurement and preservation.

To qualify for a license to practice perfusion, an individual must submit evidence either of certification as a certified perfusionist or other national certification approved by MBP or of graduation from a perfusion educational program that meets specified criteria. An individual must also meet other education or clinical requirements. An applicant who submits to the board satisfactory evidence of graduation from an approved perfusion educational program may be licensed for a single two-year term before taking the national certifying examination or another examination given or approved by MBP.

PAC comprises seven members appointed by the board and is charged with developing and recommending regulations, a code of ethics, standards of care, and continuing education requirements.

Background: An investigational device exemption from the FDA allows an investigational device to be used in a clinical study in order to collect safety and effectiveness data. A “humanitarian use device” is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. A federally designated organ procurement organization (OPO) is the only organization that can recover organs from deceased donors for transplantation. According to the Association of Organ Procurement Organizations, there are 58 federally designated OPOs. OPOs are regulated by multiple government agencies for both medical and ethical standards. Existing OPOs have not previously been required to use licensed perfusionists.

According to the University of Maryland School of Medicine, while the University of Maryland Medical Center uses licensed perfusionists for heart bypass and other procedures with living patients, it does not utilize perfusionists in the transplant process when organs have been recovered from a human body and are being preserved prior to transplantation. It is unclear whether “organ procurement and preservation” as part of the practice of perfusion was intended to apply to the preservation of organs when there is no living patient involved.

Maryland is 1 of 18 states that regulate the practice of perfusion. While regulations regarding the practice of perfusion have been drafted, they have not yet taken effect. According to MBP, there are 75 licensed perfusionists in Maryland. The issue of whether

an individual engaged in the evaluation, procurement, or preservation of organs *outside of the human body* should be subject to licensure as a perfusionist has been brought before PAC and been referred to the full board. The issue is scheduled to be heard by MBP at its April 30, 2014 meeting.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): U.S. Food and Drug Administration, Association of Organ Procurement Organizations, Department of Health and Mental Hygiene, University of Maryland Medical System, Department of Legislative Services

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