Maryland General Assembly
Department of Legislative Services

Proposed Regulations
Department of Health and Mental Hygiene

(DLS Control No.16-101)

Overview and Legal and Fiscal Impact

The regulations reduce or eliminate certain health-related licensing and permitting fees, including fees for comprehensive care facilities, hospitals and related institutions, free standing medical facilities, residential treatment centers for emotionally disturbed children and adolescents, health care staff agencies, home health agencies, assisted living programs, hospice care programs, medical and forensic laboratories, day care for the elderly and adults with a medical disability, and the Advance Directive Registry.

The regulations present no legal issues of concern.

General fund revenues decline by an estimated $1.75 million annually beginning in fiscal 2017 due to a reduction in or elimination of various fees. General fund expenditures are not materially affected.

Regulations of COMAR Affected

Department of Health and Mental Hygiene:

Hospitals: Comprehensive Care Facilities and Extended Care Facilities:
COMAR 10.07.02.03
Nursing Staff Agencies: COMAR 10.07.03.05 and .06
Related Institutions - Residential Treatment Centers for Emotionally Disturbed Children and Adolescents: COMAR 10.07.04.03
Freestanding Medical Facilities: COMAR 10.07.08.05
Home Health Agencies: COMAR 10.07.10.04
Assisted Living Programs: COMAR 10.07.14.07
License Fee Schedule for Hospitals and Related Institutions: COMAR 10.07.15.02 and .03
Hospice Care Programs: COMAR 10.07.21.04
Laboratories: Medical Laboratories - Licenses: COMAR 10.10.03.03, .04 and 06
Medical Laboratories - Fees: COMAR 10.10.04.02 and .03
Medical Laboratories - Public Health HIV Testing Programs: COMAR 10.10.12.04
Adult Health: Day Care for the Elderly and Adults with a Medical Disability:
COMAR 10.12.04.04 and .05
Advance Directive Registry: Advance Directive Registry: COMAR 10.23.01.05 and .06
Forensic Laboratories: Responsibilities, Accreditations, and Audits: COMAR 10.51.02.01
License and Fees: COMAR 10.51.03.02-.04

Legal Analysis

Background

On September 15, 2015, Governor Larry Hogan announced a plan to reduce or eliminate a number of fees across State government. Governor Hogan announced a second round of fee reductions or eliminations on May 12, 2016. This regulation is part of the second round of reductions or eliminations. Additional information regarding Governor Hogan's fee reduction initiative may be found here.

Summary of Regulations

The regulations reduce or eliminate licensing and permitting fees for certain health-related facilities, agencies, programs, and laboratories. The fees reduced or eliminated under the regulations are summarized in **Exhibit 1** within the fiscal analysis below.

Legal Issues

The regulations present no legal issues of concern.

Statutory Authority and Legislative Intent

The Department of Health and Mental Hygiene cites § 6-303 of the Environment Article; §§ 2-104, 5-620 through 5-626, 14-206, 14-304, 17-202, 17-204 through 17-210, 17-212, 17-502, 17-503, 17-505, 17-506, 17-508, 17-510, 19-308, 19-308.1, 19-320, 19-323, 19-404, 19-903, and 19-1401 et seq.; Title 17, Subtitle 2A; and Title 19, Subtitle 3A, Subtitle 18, and Subtitle 20 of the Health – General Article; § 14-110.1 of the Public Safety Article; and § 10-226 of the State Government Article as statutory authority for the regulations.

More specifically, § 2-104 of the Health – General Article authorizes the Secretary of Health and Mental Hygiene to adopt regulations to carry out provisions of law that are within the jurisdiction of the Secretary.

Section 5-621 of the Health – General Article authorizes the Secretary to adopt regulations to ensure the efficient operation of the Advance Directive Registry. Section 5-622 requires the Secretary, by regulation, to set a fee for any service of the Registry. Under the section, the fees set by the Secretary may not, in the aggregate, exceed the department's costs to establish and operate the Registry.

Section 14-206 of the Health – General Article requires the department to adopt regulations that set the standards necessary for the welfare and safety of elderly individuals who receive care in day care centers for the elderly. Section 14-304 requires the department to provide for licensing of day care centers for adults and to adopt and enforce regulations that set the standards necessary for the welfare and safety of medically handicapped adults who receive care in such day care centers.

Section 17-202 of the Health – General Article requires the Secretary to adopt regulations that set standards and requirements for medical laboratories. The section also requires the Secretary to conduct an inspection of each medical laboratory for which a license to operate is sought and to conduct an inspection periodically of each medical laboratory for which a license has been issued. Section 17-204 requires the Secretary to set fees for licenses to offer or perform medical laboratory tests or examinations. Section 17-205 requires a person to hold a license issued by the Secretary before the person may offer or perform medical laboratory tests or examinations in the State or offer or perform medical laboratory tests or examinations on specimens acquired from health care providers in the State at a medical laboratory located outside the State. The section also authorizes the Secretary to issue a letter of exception to a laboratory that performs only limited medical laboratory tests or examinations and meets certain requirements adopted in certain regulations. Section 17-207 requires an applicant for a license to operate a medical laboratory to pay to the department an application fee set by the Secretary. Section 17-209 authorizes renewal of a license to operate a medical laboratory if the licensee pays to the department a renewal fee set by the Secretary and any outstanding licensing or proficiency testing fees. Section 17-211 requires a licensee to enroll in and continue to demonstrate satisfactory performance in a proficiency testing program.

Section 17-502 of the Health – General Article requires a person to obtain a permit from the department before offering to provide a test to detect the amount of cholesterol in an individual's blood and conducting the test outside a permanently located medical laboratory issued a permit or excepted from a permit under specified provisions of law. Section 17-504 requires the Secretary to adopt regulations to implement provisions of law governing cholesterol testing. Section 17-506 requires an applicant for a permit to pay to the department an application fee set by the Secretary.

Section 17-2A-02 of the Health – General Article requires the Secretary to adopt regulations that set standards and requirements for forensic laboratories. Under the section, the regulations must require the Secretary to charge fees that may not exceed the actual direct and indirect costs to the department to carry out provisions of law governing forensic laboratories. Section 17-2A-04 requires a forensic laboratory to hold a license issued by the Secretary before the laboratory may offer or perform forensic analysis in the State. Under the section, the Secretary must issue a letter of exception to a laboratory that performs only limited forensic analysis and meets requirements in certain regulations. The section also authorizes the Secretary to grant an out-of-state forensic laboratory a waiver from the licensure requirements established in provisions of law that govern forensic laboratories. Section 17-2A-06 requires an applicant for a license to operate a forensic laboratory to pay an application fee set by the Secretary. Section 17-2A-08 authorizes a licensee to renew its license for an additional term if the licensee pays to the department a renewal fee set by the Secretary.

Section 19-308 of the Health – General Article requires the Secretary to adopt reasonable regulations that set standards of services for hospitals, related institutions, and residential treatment centers. The section also requires the Secretary to have an inspection made of such facilities for which a license is sought to assure compliance with the standards set by the Secretary. Section 19-320 requires an applicant for a license to operate a hospital or related institution to pay

to the Secretary an application fee set by the Secretary in regulations. Section 19-324 authorizes renewal of a license to operate a hospital or a related institution if the licensee pays to the Secretary a fee set by the Secretary in regulations and meets other requirements.

Section 19-3A-03 requires the department to issue a license to a freestanding medical facility that meets licensure requirements established under statute and receives a certificate of need from the Maryland Health Care Commission.

Section 19-404 of the Health – General Article requires the department to adopt regulations that set standards for the care, treatment, health, safety, welfare, and comfort of patients of home health agencies. The regulations adopted under the section must provide for the licensing of home health agencies and annual license renewal.

Section 19-903 of the Health – General Article requires the Secretary to adopt regulations to carry out provisions of law governing hospice care facilities.

Section 19-1804.1 of the Health – General Article requires a person to be licensed by the department to conduct, operate, or maintain an assisted living program in the State. The section also requires an applicant for licensure to submit a fee established in regulation adopted by the department under a specified provision of law. Section 19-1805 requires the department, in consultation with representatives of the affected industry and advocates for residents of the facilities and with the approval of the Department of Aging and the Department of Human Resources, to adopt regulations to implement provisions of law governing assisted living facilities. The regulations adopted must require the Secretary to charge fees in a manner that will produce funds not to exceed the actual direct and indirect costs to the department and maintaining the licensure program for assisted living programs.

Section 19-2001 of the Health – General Article requires a health care staff agency to be licensed by the Office of Health Care Quality and authorizes renewal of a license if an agency pays to the Office the renewal fee set by the Office and is otherwise entitled to be licensed.

The remaining cited authority is not relevant to these regulations.

Although not cited by the department, § 19-905 of the Health – General Article requires a person to be licensed by the Secretary to operate a hospice care program. In addition, § 19-907 of the Health – General Article requires an applicant for a license to pay to the Secretary an application fee established by the Secretary.

With the addition of §§ 19-905 and 19-907 of the Health – General Article, the relevant cited authority is correct and complete. The regulations comply with the legislative intent of the law.

Technical Corrections and Special Notes

Chapter 510 of 2016 repeals the Advance Directive Registry and the requirement for the Secretary to set fees by regulation for any service of the Registry, effective October 1, 2016. The department, however, has never collected any fees for using the services of the Registry.

Fiscal Analysis

General fund revenues decline by an estimated $1.75 million annually beginning in fiscal 2017 due to a reduction in or elimination of various fees. General fund expenditures are not materially affected.

Agency Estimate of Projected Fiscal Impact

The regulations reduce or eliminate multiple fees associated with licensure (or permitting) of various health care providers by the Office of Health Care Quality (OHCQ). **Exhibit 1** displays each affected license/permit, the license/permit term, the current and proposed fees (or indication that a fee is being eliminated), and the estimated annualized revenue reduction associated with each fee.

OHCQ advises that, in total, the proposed fee reductions/eliminations decrease general fund revenues by an estimated $1,750,175 annually beginning in fiscal 2017. This reflects the average, annualized decrease in license/permit fee revenues and assumes OHCQ issues the same number and type of licenses/permits in future years as it did in fiscal 2015. The estimate does not account for growth or attrition. For those licenses/permits that are issued on a multi-year basis (comprehensive/extended care facilities, freestanding medical facilities, hospice care programs, rapid HIV antibody testing and HCV testing, medical laboratories, forensic laboratories, and day care for the elderly and adults with a medical disability – better known as adult medical day care), the estimated impact represents the proposed decrease in fee revenue multiplied by the number of providers licensed/permitted in fiscal 2015, divided by the number of years in each license/permit term. OHCQ advises that specific data on the number of multi-year licenses/permits issued and renewed in each fiscal year is not available. Thus, the Department of Legislative Services generally concurs with the *overall* estimated revenue reduction but notes that the reduction/elimination of fees for licenses/permits issued on a multi-year basis may result in fluctuations in revenue from year to year due to the likelihood for a higher proportion of multi-year licenses/permits to be renewed in a particular fiscal year (as discussed in more detail below).

OHCQ advises that costs associated with licensing and permitting activities are supported by general and federal funds and the collected fees accrue to the general fund. Thus, the revenue reductions have no direct programmatic impact. Likewise, staffing within OHCQ is not expected to be affected. The Department of Legislative Services concurs. The Department of Legislative Services also notes that certain of the fees may have been paid by State agencies; even so, any reduction in State expenditures is not material. Moreover, because the fee for replacement of slides damaged during proficiency testing of cytotechnologists is being eliminated, the department likely incurs additional minimal expenditures for this purpose.

Exhibit 1
Fee Reductions and Eliminations and the Impact on General Fund Revenues

License/Permit	Term	Current Fee	Proposed Fee	Annualized Revenue Reduction
Comprehensive/Extended Care Facilities	2 Years			$690,600
1-50 Beds Initial and Renewal License		$3,000	Eliminated	
51-99 Beds Initial and Renewal License		$5,000	Eliminated	
100+ Beds Initial and Renewal License		$7,000	Eliminated	
Transitional Care Units Initial and Renewal License		$600	Eliminated	
Health Care Staff Agencies	1 Year			$86,550
Initial and Renewal License		$100	Eliminated	
New License Issued for Change(s) in Information		$150	Eliminated	
Residential Treatment Centers for Emotionally Disturbed Children and Adolescents				
Initial and Renewal License	1 Year	$10	Eliminated	$20
Freestanding Medical Facilities				
Renewal License	3 Years	$3,000	$2,000	$1,000
Home Health Agencies				
Initial and Renewal License	1 Year	$350	Eliminated	$19,600
Assisted Living Programs	1 Year			$357,980
1-4 Beds Annual License		$200	$50	
5-15 Beds Annual License		$300	$75	
16-49 Beds Annual License		$450	$125	
50-99 Beds Annual License		$650	$165	
100-149 Beds Annual License		$1,000	$250	
150+ Beds Annual License		$1,500	$375	
Hospitals and Related Institutions – Annual License	1 Year			$6,654
Intermediate Care Facility for Individuals with Intellectual Disabilities		$3/Bed	Eliminated	
Residential Treatment Center		$1/Bed	Eliminated	
Health Care Facility within Correctional Institution		$2/Bed	Eliminated	
Hospice Care Programs				
Initial and Renewal License	3 Years	$300	Eliminated	$2,700
Day Care for the Elderly and Adults with a Medical Disability				
Initial and Renewal License	2 Years	$200 + $12 x Licensed Capacity	Eliminated	$72,036
Advance Directive Registry				
Registering or Amending an Advance Directive*	N/A	$10	Eliminated	$0
Rapid HIV Antibody Testing and HCV Testing				
Initial and Renewal License	2 Years	$50	Eliminated	$900
Subtotal				*$1,238,040*

License/Permit	Term	Current Fee	Proposed Fee	Annualized Revenue Reduction
Medical Laboratories				$506,655
Permits	2 Years			
Amended Permit		$50	Eliminated	
Letter of Exception – Limited Testing**		$100	Eliminated	
Letter of Exception but 1+ Tests Require Permit		$200	Eliminated	
General Permit				
Partial Fee for ≤ 3 Disciplines		$50	Eliminated	
Partial Fee > 3 Disciplines		$200	Eliminated	
Licensing Fee Per Discipline		$200	Eliminated	
Cholesterol Testing Permit				
< 21 Testing Events at < 6 Testing Sites		$250	Eliminated	
21 to 40 Events or 6 to 11 Sites		$350	Eliminated	
> 40 Events or ≥ 12 Sites		$450	Eliminated	
Proficiency Testing	1 Year			
Gynecologic Cytology Testing (Base Amount)		$250	Eliminated	
+ Per Gynecologic Slide (In Prior Calendar Year)		2¢/slide	Eliminated	
+ Per Cytotechnologist Examinee Employed		$50	Eliminated	
Cytotechnologist Retesting		$50	Eliminated	
Newly Hired Cytotechnologist Testing		$50	Eliminated	
Slide Replacement (Due to Damage During Testing)		$150	Eliminated	
Forensic Laboratories	3 Years			$5,480
Amended or Replacement Permit		$50	Eliminated	
Waiver Request		$60	Eliminated	
Accredited				
Initial and Renewal Application		$150	Eliminated	
Per Discipline at Each Site		$90	Eliminated	
Non-Accredited (In-State)				
Initial and Renewal Application		$300	Eliminated	
Per Discipline at Each Site		$300	Eliminated	
Non-Accredited (Out-of-State)				
Initial and Renewal Application		$1,000	Eliminated	
Per Discipline at Each Site		$300	Eliminated	
Provisional License				
Addition of New Discipline		$200	Eliminated	
Addition of New Subdiscipline		$60	Eliminated	
Letter of Permit Exception Application				
Per Discipline		$300	Eliminated	
Per Subdiscipline		$180	Eliminated	
Subtotal				*$512,135*
Total				**$1,750,175**

*As the fee to register or amend an advance directive with the registry has not been charged, there is no impact from its elimination. **Represents limited testing for (1) rare diseases and (2) POL/POCL (physician's office lab/point of care letter); the same fee is currently charged for both types of limited testing letters of exception.

Source: Department of Health and Mental Hygiene; Department of Legislative Services

Impact on Budget

General fund revenues decline by an estimated $1.75 million annually beginning in fiscal 2017. Even so, there is no material impact on the State operating or capital budget and any impact on general fund expenditures is assumed to be minimal.

Agency Estimate of Projected Small Business Impact

OHCQ advises that the regulations have a meaningful economic impact on small businesses because the proposed fee reductions/eliminations result in significant savings for providers who are small businesses in Maryland. However, OHCQ advises that it is unknown what percentage of affected providers constitute small businesses. The Department of Legislative Services concurs that the impact is beneficial but notes that the impact of the fee reductions/eliminations for most small business licensees is likely to be relatively minimal.

Additional Comments

The Department of Legislative Services reviewed data available on OHCQ's website regarding the anticipated renewal dates of three of the seven types of providers with multi-year licenses/permits – comprehensive/extended care facilities, hospice care programs, and day care for the elderly and adults with a medical disability. For comprehensive/extended care facilities, which have a two-year license term, an estimated 47% of licensees will renew in fiscal 2017 and 53% will renew in fiscal 2018. For hospice care programs, which have a three-year license term, an estimated 58% of licensees will renew in fiscal 2017, 19% in fiscal 2018, and 23% in fiscal 2019. For day care for the elderly and adults with a medical disability, which has a two-year license term, an estimated 47% of licensees will renew in fiscal 2017 and 53% will renew in fiscal 2018. Data on the remaining four types of multi-year licenses/permits was not available. OHCQ advises that the license dates contained in its dataset are drawn from a centralized source, but they are not audited by OHCQ. Due to a lack of complete or reliable data, specific annual estimates of the total revenue reductions associated with multi-year licenses/permits cannot be provided at this time. However, the Department of Legislative Services advises that the impact of the fee reductions/eliminations may vary significantly by year compared with the annualized estimate.

In addition, Governor Hogan's announcement of fee reductions included elimination of a $100 fine for health care staff agencies for failure to notify the department of any change in agency ownership, name, or address within 30 calendar days of the change. These regulations did not amend or repeal that provision; it is unclear whether a separate regulation will be submitted by the department to do so. It is also unclear whether the department's estimate for other provisions affecting health care staff agencies incorporates the impact of eliminating the fine. Regardless, the Department of Legislative Services advises that the impact is likely minimal and that it may be the intention of the department to simply administratively choose to no longer assess the fine because the current regulation *authorizes* its assessment (rather than requiring assessment of the fine).

Finally, the regulations submitted by the department eliminate the $50 fee charged to medical laboratories for an amended permit; this fee was not included in the Governor's announced fee reductions. Any impact from its elimination is assumed to be negligible.

Contact Information

Legal Analysis: Patrick D. Carlson – (410) 946/(301) 970-5350
Fiscal Analysis: Nathan W. McCurdy – (410) 946/(301) 970-5510