

MARYLAND REGISTER

Proposed Action on Regulations

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee	TO BE COMPLETED BY DSD
	05/20/2016	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 6/24/2016

2. COMAR Codification

Title	Subtitle	Chapter	Regulation
10	07	02	03
10	07	03	05 and .06
10	07	04	03
10	07	08	05
10	07	10	04
10	07	14	07
10	07	15	02 and .03
10	07	21	04
10	10	03	03, .04 and 06
10	10	04	02 and .03
10	10	12	04
10	12	04	04 and .05
10	23	01	05 and .06
10	51	02	01
10	51	03	02-.04

3. Name of Promulgating Authority

Department of Health and Mental Hygiene

4. Name of Regulations Coordinator

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6. Check applicable items: New Regulations Amendments to Existing Regulations

Date when existing text was downloaded from COMAR online: May 6, 2016.

 Repeal of Existing Regulations Recodification Incorporation by Reference of Documents Requiring DSD Approval Reproposal of Substantively Different Text:

: Md. R

(vol.) (issue) (page nos) (date)

Under Maryland Register docket no.: --P.

7. Is there emergency text which is identical to this proposal: Yes No**8. Incorporation by Reference** Check if applicable: Incorporation by Reference (IBR) approval form(s) attached and 18 copies of documents proposed for incorporation submitted to DSD. (Submit 18 paper copies of IBR document to DSD and one copy to AELR.)**9. Public Body - Open Meeting** OPTIONAL - If promulgating authority is a public body, check to include a sentence in the Notice of Proposed Action that proposed action was considered at an open meeting held pursuant to General Provisions Article, §3-302(c), Annotated Code of Maryland. OPTIONAL - If promulgating authority is a public body, check to include a paragraph that final action will be considered at an open meeting.**10. Children's Environmental Health and Protection** Check if the system should send a copy of the proposal to the Children's Environmental Health and Protection Advisory Council.

11. Certificate of Authorized Officer

I certify that the attached document is in compliance with the Administrative Procedure Act. I also certify that the attached text has been approved for legality by Paul Ballard, Assistant Attorney General, (telephone #410-767-6918) on May 9, 2016. A written copy of the approval is on file at this agency.

Name of Authorized Officer

Van T. Mitchell

Title

Secretary

Telephone No.

410-767-6500

Date

May 11, 2016

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 07 HOSPITALS

10.07.02 Comprehensive Care Facilities and Extended Care Facilities

Subtitle 07 HOSPITALS

10.07.03 Health Care Staff Agencies

Subtitle 07 HOSPITALS

10.07.04 Related Institutions — Residential Treatment Centers for Emotionally Disturbed Children and Adolescents

Subtitle 07 HOSPITALS

10.07.08 Freestanding Medical Facilities

Subtitle 07 HOSPITALS

10.07.10 Home Health Agencies

Subtitle 07 HOSPITALS

10.07.14 Assisted Living Programs

Subtitle 07 HOSPITALS

10.07.15 [License Fee Schedule] Application for Hospitals and Related Institutions

Subtitle 07 HOSPITALS

10.07.21 Hospice Care Programs

Subtitle 10 LABORATORIES

10.10.03 Medical Laboratories — Licenses

Subtitle 10 LABORATORIES

10.10.04 Medical Laboratories [— Fees]

Subtitle 10 LABORATORIES

10.10.12 Medical Laboratories — Public Health HIV Testing Programs

Subtitle 12 ADULT HEALTH

10.12.04 Day Care for the Elderly and Adults with a Medical Disability

Subtitle 23 ADVANCE DIRECTIVE REGISTRY

10.23.01 Advance Directive Registry

Subtitle 51 FORENSIC LABORATORIES

10.51.02 Responsibilities, Accreditations, and Audits

Subtitle 51 FORENSIC LABORATORIES

10.51.03 Licenses [and Fees]

Authority: See proposal.

Notice of Proposed Action

□

The Secretary of Health and Mental Hygiene proposes to :

- 1) Amend Regulation .03 under COMAR 10.07.02 Comprehensive Care Facilities and Extended Care Facilities;
- 2) Amend Regulations .05 and .06 under COMAR 10.07.03 Health Care Staff Agencies;
- 3) Amend Regulation .03 under COMAR 10.07.04 Related Institutions — Residential Treatment Centers for Emotionally Disturbed Children and Adolescents;
- 4) Amend Regulation .05 under COMAR 10.07.08 Freestanding Medical Facilities;
- 5) Amend Regulation .04 under COMAR 10.07.10 Home Health Agencies;
- 6) Amend Regulation .07 and under COMAR 10.07.14 Assisted Living Programs;
- 7) Amend Regulation .02 and Repeal Regulation .03 under COMAR 10.07.15 License Fee Schedule for Hospitals and Related Institutions;
- 8) Amend Regulation .04 under COMAR 10.07.21 Hospice Care Programs;
- 9) Amend Regulation .03, .04, and .06 under COMAR 10.10.03 Medical Laboratories — Licenses;
- 10) Amend Regulations .02 and Repeal Regulation .03 under COMAR 10.10.04 Medical Laboratories — Fees;
- 11) Amend Regulation .04 under COMAR 10.10.12 Medical Laboratories — Public Health HIV Testing Programs;
- 12) Amend Regulation .04 and .05 under COMAR 10.12.04 Day Care for the Elderly and Adults with a Medical Disability;
- 13) Amend Regulation .05 and Repeal Regulation .06 under COMAR 10.23.01 Advance Directive Registry Fee;
- 14) Amend Regulation .01 under COMAR 10.51.02 Responsibilities, Accreditations, and Audits; and
- 15) Amend Regulation .02 and .03 and Repeal Regulation .04 under COMAR 10.51.03 Forensic Laboratories: Licenses and Fees.

Statement of Purpose

The purpose of this action is to eliminate or reduce the licensing fees for the regulated industries listed in the Notice of Proposed Action.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact.

The reduction and elimination of the various fees proposed will accrue cost savings to various health care providers who are required to obtain initial and renewal licenses from the Department of Health and Mental Hygiene.

Specifically, the following provider types will receive annual fee decreases as listed below.

- Comprehensive care facilities \$690,600
- Health care staffing agencies \$86,550
- Residential Treatment Centers for emotionally disturbed children and adolescents \$20
- Freestanding medical facilities \$1,000
- Home health agencies \$19,600
- Assisted living facilities \$357,980
- Intermediate care facility for individuals with intellectual disabilities \$6,654
- Hospice care program \$2,700
- Clinical laboratories \$506,655
- Public health HIV testing \$900
- Day care for elderly adults with medical disabilities \$72,036
- Forensic laboratories \$5,480

II. Types of Economic Impact.	Revenue (R+/R-) Expenditure (E+/E-)	Magnitude
A. On issuing agency:	(R-)	\$1,750,175
B. On other State agencies:	NONE	
C. On local governments:	NONE	
	Benefit (+) Cost (-)	Magnitude
D. On regulated industries or trade groups:	(+)	\$1,750,175
E. On other industries or trade groups:	NONE	
F. Direct and indirect effects on public:	NONE	

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

A. This estimate is based on elimination and reductions of fees collected for the 12 provider categories encompassed by the cited COMAR regulations in the previous fiscal year (2015), and assumes the same number and type of applicant when the regulations become effective. This includes a decrease in annual fee collections of \$357,980 from the proposed 75 percent reduction in fees for Assisted Living Facilities, as well as a

\$1,000 annual decrease in fee collections from the proposed 33 percent reduction in fees for freestanding medical facilities. All other fees associated with provider types contemplated in this proposal will be eliminated All fees collected are deposited into the General Fund.

D. See A above.

Economic Impact on Small Businesses

The proposed action has a meaningful economic impact on small business. An analysis of this economic impact follows.

Assisted Living facility operators will see a 75 percent decrease in initial and renewal license costs. As a large proportion of Assisted Living providers in Maryland are small businesses, this will result in a significant positive economic impact to the owners.

Operators of freestanding medical facilities will see a reduction of \$1,000 for 3-year license renewals. The Department notes that the three freestanding medical facilities in Maryland are associated with larger medical institutions and would not be considered small businesses.

The elimination of all fees set forth in the remaining COMAR regulations listed in this proposal will have a significant positive impact on small businesses. Small business owners constitute varying percentages of the operators of facilities in the industries affected by the fee eliminations, and represent hundreds of individual businesses in the State of Maryland.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499; TTY:800-735-2258, or email to dhmh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through July 25, 2016. A public hearing has not been scheduled.

Economic Impact Statement Part C

A. Fiscal Year in which regulations will become effective: FY 2017

B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?

C. If 'yes', state whether general, special (exact name), or federal funds will be used:

D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:

E. If these regulations have no economic impact under Part A, indicate reason briefly:

F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.

G. Small Business Worksheet:

Attached Document:

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 07 HOSPITALS

10.07.02 Comprehensive Care Facilities and Extended Care Facilities

Authority: Health-General Article, §§19-308, 19-308.1, 19-323, and 19-1401 et seq.; Public Safety Article, §14-110.1; Annotated Code of Maryland

10.07.02.03 (5/6/2016)

.03 Licensing Procedure.

A. Application for License.

(1) (text unchanged)

[(2) A nonrefundable 2-year license fee shall accompany the application based on the following payment schedule:

(a) 1—50 beds: \$3,000;

(b) 51—99 beds: \$5,000;

(c) 100+ beds: \$7,000; and

(d) Transitional care units: \$600.]

[(3)] (2)—[(6)] (5) (text unchanged)

[(7) A facility that is a transitional care unit with fewer than 50 beds and that is affiliated with a licensed Maryland hospital shall pay the 2-year license fee for a transitional care unit.]

[(8)] (6)—[(9)] (7) (text unchanged)

B. Restrictions of License.

(1)—(3) (text unchanged)

(4) Renewal of License.

(a) (text unchanged)

(b) The renewal application shall be[:

(i) Submitted] *submitted* on forms provided by the Secretary[; and

(ii) Accompanied by a nonrefundable 2-year license renewal fee based on the payment schedule in §A(2) of this regulation].

[(5) A facility that is a transitional care unit with fewer than 50 beds and affiliated with a licensed Maryland hospital shall pay the 2-year license renewal fee for a transitional care unit.]

[(6)] (5)—[(7)] (6) (text unchanged)

10.07.03 Health Care Staff Agencies

Authority: Health-General Article, Title 19, Subtitle 20, Annotated Code of Maryland

10.07.03.05

.05 Licensing Procedure.

A. Application for Licensure.

(1)—(2) (text unchanged)

(3) Along with the application, the applicant shall submit a[

(a) Nonrefundable 1-year license fee of \$100 made payable to the Department; and

(b) Copy] *copy* of the agency's policies and procedures as specified in Regulation .08 of this chapter.

B.—C. (text unchanged)

D. License Renewal.

(1) (text unchanged)

(2) Before a license expires, the agency may renew its license for an additional term, if the agency:

(a) (text unchanged)

[(b) Pays to the Office the \$100 license renewal fee; and]

[(c)] (b) (text unchanged)

(3) (text unchanged)

E.—G. (text unchanged)

10.07.03.06

.06 Changes to Licensure Information.

A. (text unchanged)

B. Any change in agency ownership, name, or address requires the issuance of a new license [and a fee of \$150]. If the sale, transfer, assignment, or lease of an agency causes a change in the person or persons who control or operate the agency, the agency shall be considered a "new agency" and the new owner shall comply with all regulations of this chapter when applying for a new license.

C. (text unchanged)

10.07.04 Related Institutions — Residential Treatment Centers for Emotionally Disturbed Children and Adolescents

Authority: Health-General Article, §19-308, Annotated Code of Maryland

10.07.04.03

.03 Licensing Procedure.

A. Application. Applicants shall conform to the following:

(1)—(2) (text unchanged)

(3) [Each application shall be accompanied by a fee of \$10]. All licenses issued shall expire 1 year from the date of issuance unless revoked. [Fees will not be refunded.]

(4) The applicant for an original license shall submit the following, and insure that current copies are on file with the department:

(a) (text unchanged)

(b) [(list] *List* of officers and Board members with addresses;

(c)—(n) (text unchanged)

(5) Renewal. Application for the renewal of the license shall be made each year at least 30 days before expiration of issued license, submitted on forms provided by the Secretary[, and accompanied by the \$10 license renewal fee. by the \$10 license renewal fee].

B.—F. (text unchanged)

10.07.08 Freestanding Medical Facilities

Authority: Health-General Article, §2-104 and Subtitle 19-3A, Annotated Code of Maryland

10.07.08.05

.05 Renewal of License.

A.—B. (text unchanged)

C. The application *fee* for license renewal shall be accompanied by a nonrefundable 3-year license renewal fee of [\$3,000] \$2,000.

10.07.10 Home Health Agencies

Authority: Health-General Article, §19-404, Annotated Code of Maryland

10.07.10.04

.04 General Licensure Provisions.

A. (text unchanged)

B. Application for License. An agency desiring to conduct, operate, or maintain a home health agency in the State shall file an application with the Secretary, on a form provided by the Secretary. [A nonrefundable licensing fee of \$350 shall accompany the application for licensure.]

C. Renewal of License. An agency shall file an application for renewal of the license at least 60 days before expiration of the issued license[,] and submitted on forms provided by the Secretary [and accompanied by a nonrefundable license renewal fee of \$350].

D.—G. (text unchanged)

10.07.14 Assisted Living Programs

Authority: Health-General Article, Title 19, Subtitle 18, Annotated Code of Maryland

10.07.14.07

.07 Licensing Procedure.

A. Application for License.

(1)—(2) (text unchanged)

(3) Fees. The annual license fee schedule for assisted living programs is as follows:

(a) 1—4 beds: [\$200] \$50 annually;

(b) 5—15 beds: [\$300] \$75 annually;

(c) 16—49 beds: [\$450] \$125 annually;

(d) 50—99 beds: [\$650] \$165 annually;

(e) 100—149 beds: [\$1,000] \$250 annually; and

(f) 150 plus beds: [\$1,500] \$375 annually.

(4)—(5) (text unchanged)

B.—D. (text unchanged)

10.07.15 [License Fee Schedule] Application for Hospitals and Related Institutions

Authority: Health-General Article, §§19-320 and 19-323, Annotated Code of Maryland

10.07.15.02

.02 Application [and Fee] Requirements.

A. Any person desiring to open a related institution or to continue the operation of a related institution shall[:

A. File] file an application with the Secretary, on a form provided by the Secretary.

B. Applications on behalf of a corporation, association, or governmental unit or agency shall be made by two officers of the corporation, association, or governmental unit or agency and names of their board members shall be submitted.

C. Ownership of property, real estate, and equipment shall be disclosed if it is other than the licensee's.

D. The names of persons holding 2 percent or more of the stock or assets shall be disclosed.

[B. Submit to the Department the fee as prescribed under Regulation .03.]

10.07.21 Hospice Care Programs

Authority: Health-General Article, §19-903, Annotated Code of Maryland

10.07.21.04

.04 Application Procedure.

A. (text unchanged)

B. [To apply for an initial license or renewal of a license, an applicant shall:

(1) Submit an application to the Secretary on a form provided by the Secretary; and

(2) Pay to the Secretary an application fee of \$300.] *The applicant shall submit an application for initial license or renewal of a license on a form provided by the Secretary.*

C.—E. (text unchanged)

Subtitle 10 LABORATORIES

10.10.03 Medical Laboratories — Licenses

Authority: Environment Article, §6-303; Health-General Article, §§2-104(b), 17-202, 17-205—17-210, 17-212, 17-502, 17-503, 17-505, 17-508, and 17-510; Annotated Code of Maryland

10.10.03.03 (5/11/16)

.03 Permits.

A.—B. (text unchanged)

C. Regulatory Requirements. A person operating a medical laboratory under a permit shall:

(1) Obtain, complete, and submit permit applications [and fees] as prescribed in this chapter and COMAR 10.10.04;

(2)—(5) (text unchanged)

10.10.03.04

.04 Letter of Exception and Permit—Administrative Procedures.

A. (text unchanged)

B. Application—Evaluation and Billing.

(1) The OHCQ shall review and evaluate an application in accordance with the standards and requirements of this subtitle to determine if:

(a) An] *an* application is complete[; and].

[(b) A] (2) *The OHCQ shall review and evaluate an application in accordance with the standards and requirements of this subtitle to determine if the laboratory is eligible for a:*

[(i)] (a)—[(iii)] (c) (text unchanged)

[(2) After reviewing and evaluating an application, the OHCQ shall bill a laboratory and the laboratory shall immediately pay the applicable remaining balance of the licensing fee.]

C.—D. (text unchanged)

E. Amending a Permit. Except as prescribed in §D of this regulation, a licensee holding an unexpired permit who wishes to amend it shall:

(1) Submit a written request for amendment to the Secretary; *and*

[(2) Remit to the OHCQ a \$50 relicensing fee; and]

[(3)] (2) (text unchanged)

F.—G. (text unchanged)

10.10.03.06

.06 Letter of Exception—Limited Testing for Rare Diseases; Standards and Requirements.

A. Application Requirements and Testing Approval. A person required to obtain a license to operate a laboratory that chooses to operate under a letter of exception—limited testing for rare diseases shall:

(1) Submit:

(a)—(b) (text unchanged)

(c) Documentation of the rare disease testing offered or performed, including but not limited to:

(i)—(v) (text unchanged)

(vi) Additional information necessary for determining eligibility and compliance with this subtitle; *and*

[(d) The licensing fee stated in COMAR 10.10.04.02B, unless the fee is waived as set forth in COMAR 10.10.04.01E; and]

(2) (text unchanged)

B.—E. (text unchanged)

10.10.04 Medical Laboratories [— Fees]

Authority: Health-General Article, §§17-202, 17-204, 17-205, 17-207, 17-209, 17-502, 17-503, and 17-506, Annotated Code of Maryland

10.10.04.01

.01 General.

A.—D. (text unchanged)

E. Fee Waiver. The Secretary may waive all licensing fees for a:

(1) Municipal or county health department; *or*

(2) Governmental agency that receives funding to operate from the State[; or

(3) Laboratory operating under a letter of exception—limited testing for rare diseases, if the laboratory is operated as:

(a) A not-for-profit entity; or

(b) Part of an accredited educational institution].

10.10.04.02

.02 Licensing — Letter of Exception [and Permit].

A. Letter of Exception. [Except as set forth in §C(4) of this regulation, a] A person applying for a letter of exception for a POL or POCL shall submit [a licensing fee of \$100 with] an initial application and biennially after that with each renewal application.

B. Letter of Exception — Limited Testing for Rare Diseases. A person applying for a letter of exception-limited testing for rare diseases for a laboratory shall submit [a licensing fee of \$100 with] an initial application and biennially after that with each renewal application.

[C. Permit — General.

(1) A person applying for a permit to operate a laboratory shall submit with each initial application a partial licensing fee of:

(a) \$50 when the application covers three or fewer disciplines; and

(b) \$200 when the application covers more than three disciplines.

(2) After evaluating the application for a permit, the OHCQ shall bill the person making application for the unpaid portion of a licensing fee by mailing an invoice listing the required fee as set forth in §C(3) of this regulation.

(3) A person obtaining or renewing a permit shall pay initially, and biennially after that, a licensing fee of \$200 for each discipline in which the laboratory offers to perform or performs tests.

(4) A person who qualifies for a letter of exception as set forth in COMAR 10.10.03.02 and performs one or more tests that require obtaining or renewing a permit shall pay initially, and biennially after that, a licensing fee of \$200 as set forth in §C(3) of this regulation for each discipline in which the laboratory offers to perform or performs nonexcepted tests.

(5) A person issued a permit under §C(4) of this regulation is not required to pay the partial licensing fees set forth in §C(1) of this regulation.

D. Permit — Cholesterol Testing.

(1) A person applying for a cholesterol testing permit to perform cholesterol testing at a temporary or mobile laboratory shall submit an initial licensing fee of:

(a) \$250 if there will be fewer than 21 testing events during the license year and they will be held at fewer than six testing sites;

(b) \$350 if there will be 21 to 40 testing events during the license year or they will be held at six to 11 testing sites; and

(c) \$450 if there will be more than 40 testing events during the license year or they will be held at 12 or more testing sites.

(2) A cholesterol testing permit holder shall pay an additional licensing fee equal to the difference between the initially submitted licensing fee and the higher licensing fee, as set forth under §D(1) of this regulation, when the cholesterol testing permit holder conducts more testing events or uses more testing sites than authorized in a given permit period.]

10.10.12 Medical Laboratories — Public Health HIV Testing Programs

Authority: Health-General Article, §§17-202, 17-204—17-210, Annotated Code of Maryland

10.10.12.04

.04 Public Health Testing License for Rapid HIV Antibody Testing and HCV Testing.

A.—D. (text unchanged)

E. To obtain, maintain, or renew a public health testing license, a person shall:

(1)—(2) (text unchanged)

(3) Submit to the Department:

(a) (text unchanged)

(b) The location of all testing sites; *and*

(c) (text unchanged)

[(d) A \$50 licensing fee for each initial license or license renewal, remitted as a check made payable to the Department of Health and Mental Hygiene; and]

(4) (text unchanged)

F.—G. (text unchanged)

Subtitle 12 ADULT HEALTH

10.12.04 Day Care for the Elderly and Adults with a Medical Disability

Authority: Health-General Article, §§2-104, 14-206, and 14-304; State Government Article, §10-226; Annotated Code of Maryland

10.12.04.04

.04 Licensing Procedure.

A. Letter of Interest.

(1)—(3) (text unchanged)

(4) Upon approval of the letter of interest, an application for licensure shall be submitted on the form developed by the Department [along with a licensure fee calculated under the provisions of §A(5) of this regulation].

[(5) License fee for initials and renewals.

(a) The 2-year license fee, based upon total licensed capacity of the center, shall be computed at a rate of \$200, plus \$12 times the licensed capacity of the center.

(b) The nonrefundable fee shall be payable by certified check or money order to the Department.]

B. (text unchanged)

C. Issuance of License. When the Department determines that the center has submitted a complete application, [including the required fee,] and that the center is in compliance with this chapter, the Department shall issue a license to operate the center.

D.—E. (text unchanged)

Subtitle 23 ADVANCE DIRECTIVE REGISTRY

10.23.01 Advance Directive Registry

Authority: Health-General Article, §§5-620—5-626, Annotated Code of Maryland

10.23.01.05

.05 Amendment or Revocation of a Registered Advance Directive.

A. (text unchanged)

B. The Department shall amend the file of a registrant on receipt of:

(1) An application for amendment on a form provided by the Department; *and*

[(2) The required fee, as set forth in Regulation .06 of this chapter; and]

[(3)] (2) (text unchanged)

C.—D. (text unchanged)

Subtitle 51 FORENSIC LABORATORIES

10.51.02 Responsibilities, Accreditations, and Audits

Authority: Health-General Article, Title 17, Subtitle 2A, Annotated Code of Maryland

10.51.02.01

.01 Responsibilities of the Department.

A.—C. (text unchanged)

D. Administration and Information Management. The Department shall:

(1)—(3) (text unchanged)

[(4) Set and collect fees as set forth in COMAR 10.51.03.04;] and

[(5)] (4) (text unchanged)

E. (text unchanged)

10.51.03 Licenses [and Fees]

Authority: Health-General Article, Title 17, Subtitle 2A, Annotated Code of Maryland

10.51.03.02

.02 License — Requirements.

A. Requirements. A person operating a forensic laboratory that performs one or more forensic analyses shall:

(1) Obtain, complete, and submit permit applications [and fees] as prescribed in this subtitle;

(2)—(3) (text unchanged)

B. (text unchanged)

10.51.03.03

.03 License — Administrative Procedures.

A. Application — Filing.

(1)—(2) (text unchanged)

[(3) A person shall submit with the application the nonrefundable application fee set forth in COMAR 10.51.03.04.]

B. Application — Evaluation and Billing.

[(1)] The Department shall review and evaluate an application in accordance with the standards and requirements of this subtitle to determine if the:

[(a)] (1)—[(b)] (2) (text unchanged)

[(2) After reviewing and evaluating an application, the Department shall bill a forensic laboratory, and the forensic laboratory shall immediately pay the applicable licensing fee.]

C. Application — Denial of License. If the Department determines that a forensic laboratory is not in compliance with the requirements of this subtitle and therefore cannot be issued a license, the Department shall provide to the forensic laboratory:

(1) (text unchanged)

(2) The opportunity to:

(a) Amend and resubmit the application [upon payment of a new application fee]; or

(b) (text unchanged)

D.—H. (text unchanged)

VAN T. MITCHELL

Secretary of Health and Mental Hygiene

**FEE JUSTIFICATION FOR
PROPOSED COMAR 10.07, 10.10, 10.12, 10.23 and 10.51**

(1) Explain/justify why an increase or decrease is necessary:

A decrease in fees associated with the identified COMAR titles will reduce operating costs associated with obtaining initial or renewal licensure for a variety of entities regulated by the Maryland Department of Health and Mental Hygiene.

(2) How much money is needed to operate effectively or to eliminate an operating fund deficit?

Not applicable. No funds are required to reduce the proposed fees.

(3) In what year was the most recent fee increase?

10.07.02 Comprehensive Care Facilities and Extended Care Facilities	8/24/2009
10.07.03 Health Care Staff Agencies	9/15/2015
10.07.04 Related Institutions — Residential Treatment Centers for Emotionally Disturbed Children and Adolescents	4/17/1967
10.07.08 Freestanding Medical Facilities	2/12/2007
10.07.10 Home Health Agencies	4/11/1994
10.07.14 Assisted Living Programs	8/19/2013
10.07.15 License Fee Schedule for Hospitals and Related Institutions	1/20/2014
10.07.21 Hospice Care Programs	8/10/1998
10.10.04 Medical Laboratories — Fees	12/21/2015
10.10.12 Medical Laboratories — Public Health HIV Testing Programs	4/1/2013
10.12.04 Day Care for the Elderly and Adults with a Medical Disability	12/21/2015
10.23.01 Advance Directive Registry Fee	12/6/2007
10.51.03 Licenses and Fees	5/28/2012

(4) Is the fee revenue retained by the Proposing Unit or passed through to a national organization that administers a uniform licensing exam?

The fee revenue is not retained by the Proposing Unit. It goes directly to the general fund.

(5) Describe any measures taken to mitigate the need for increased revenue:

Not applicable. The proposal is for a fee decrease on the regulated industry.

(6) Describe any special circumstances that have had an adverse impact on the Proposing Unit's operating expenses.

None.

(7) Describe any consideration given by the Proposing Unit as to the hardship a fee increase may have on the regulated profession.

Not applicable. The proposal is for a fee decrease on the regulated industry.

(8) Describe any efforts to solicit the opinions of licensees regarding the Proposing Unit's effectiveness and performance.

None.