Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Notice of Proposed Action

[17-020-P]

The Secretary of Health and Mental Hygiene proposes to:

(1) Amend Regulation .04 under COMAR 10.05.01 General Requirements;

(2) Amend Regulation .04 and repeal Regulation .21 under COMAR 10.07.01 Acute General Hospitals and Special Hospitals;

(3) Amend Regulation .05 under COMAR 10.07.03 Health Care Staff Agencies;

(4) Amend Regulations .03 under COMAR 10.07.04 Related Institutions —

Residential Treatment Centers for Emotionally Disturbed Children and Adolescents;

(5) Amend Regulation .04 under COMAR 10.07.05 Residential Service Agencies;

(6) Amend Regulation .04 under COMAR 10.07.07 Nursing Referral Service Agencies;

(7) Amend Regulations .04 and .05 under COMAR 10.07.08 Freestanding Medical Facilities;

(8) Amend Regulation .08 under COMAR 10.07.09 Residents' Bill of Rights: Comprehensive Care Facilities and Extended Care Facilities;

(9) Amend Regulation .04 under COMAR 10.07.10 Home Health Agencies;

(10) Amend Regulations .04, .05, .09, and .10 under COMAR 10.07.11 Health

Maintenance Organizations;

(11) Amend Regulations .04 and .20 under COMAR 10.07.12 Health Care Facilities Within Correctional Institutions;

(12) Amend Regulation .07 under COMAR 10.07.14 Assisted Living Programs;

(13) Amend Regulation .05 under COMAR 10.07.16 Limited Private Inpatient Facilities;

(14) Amend Regulations .03 and .04 under COMAR 10.07.17 Limited Service Hospital;

(15) Amend Regulation .04 under COMAR 10.07.18 Comprehensive Rehabilitation Facilities;

(16) Amend Regulation .04 under COMAR 10.07.20 Intermediate Care Facilities for Individuals with Intellectual Disabilities or Persons with Related Conditions (ICF/IID);

(17) Amend Regulation .04 under COMAR 10.07.21 Hospice Care Programs;

(18) Amend Regulation .02 under COMAR 10.10.03 Medical Laboratories — Licenses;

(19) Amend Regulation .04 under COMAR 10.21.16 Community Mental Health Programs — Application, Approval, and Disciplinary Processes;

(20) Amend Regulation .02 under COMAR 10.22.02 Administrative Requirements for Licensees;

(21) Amend Regulations .04 and .05 under COMAR 10.47.04 Certification Requirements; and

(22) Amend Regulations .02 and .03 under COMAR 10.51.03 Licenses.

Statement of Purpose

The purpose of this action is to improve regulatory efficiency of various health licensing requirements and standards. These amendments will:

(1) Enable the Department to accept electronic submissions of both initial applications and renewal applications and thereby improve efficiency and decrease the administrative burden on providers and the Department;

(2) Eliminate obsolete provisions concerning preauthorization requirements in hospitals;

(3) Streamline application requirements for residential treatment centers and otherwise clarify requirements;

(4) Update the visitation requirements in nursing homes to reflect the statutory requirement that a resident has the right to visit privately with the resident's domestic partner;

(5) Update and clarify provisions applicable to health maintenance organizations regarding facility inspection, patient access, medical records and certified nurse practitioners;

(6) Eliminate the application of obsolete dietary standards to health care facilities within correctional institutions; and

(7) Enable certain laboratory tests to be conducted under a letter of exception rather than requiring a license.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact. The proposed regulatory changes will have an indeterminate economic impact. This is due to the fact that they eliminate or modify a variety of requirements that simplify application procedures, update obsolete preauthorization requirements for surgical procedures and dietary standards, and enable certain laboratory tests to be performed without need for licensure across a variety of facilities and provider types. The specific economic impact of these changes cannot be accurately measured as they generally simplify administrative procedures.

> Revenue (R+/R-) Expenditure (E+/E-) Magnitude

II. Types of Economic Impact.

A. On issuing agency:B. On other State agencies:	NONE NONE	
C. On local governments:	NONE	
	Benefit (+) Cost (-)	Magnitude

(+)

Indeterminable

D. On regulated industries or trade

groups:

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.)

D. Allowing licensure and re-licensure via electronic submissions may reduce the amount of time and supplies needed to complete these processes. In addition, eliminating obsolete standards and freeing licensees from certain restrictions may lessen administrative burdens on licensees. However the actual economic impact resulting from these amendments is indeterminate.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

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 February 6, 2017. A public hearing has not been scheduled.

Subtitle 05 FREESTANDING AMBULATORY CARE FACILITIES

10.05.01 General Requirements

Authority: Health-General Article, §19-3B-01, et seq., Annotated Code of Maryland

.04 Licensing Procedure.

A. A person desiring to operate a facility shall:

(1) (text unchanged)

(2) File an application on a *written or electronic* form provided by the Department;

(3)—(4) (text unchanged)

B.-H. (text unchanged)

I. Renewal of License.

(1) At least 60 days before a license expires, the licensee shall submit a renewal application to the Secretary on a written or electronic form provided by the Department.

(2) (text unchanged)

Subtitle 07 HOSPITALS

10.07.01 Acute General Hospitals and Special Hospitals

Authority: Health-General Article, §§19-308, 19-320, and 19-323, Annotated Code of Maryland

.04 Licensure Application Procedure.

A. A person desiring to open a hospital, to continue the operation of an existing hospital, or to change the classification of an existing hospital shall file an application with the Secretary, on a *written or electronic* form provided by the Secretary. An application shall state the classification of hospital for which a license is sought.

B. (text unchanged)

C. License Renewal. An application for the renewal of the license on a written or electronic form provided by the Secretary shall be made:

(1)—(2) (text unchanged)

D.—F. (text unchanged)

10.07.03 Health Care Staff Agencies

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

.05 Licensing Procedure.

A. Application for Licensure.

(1) A person desiring to refer a health care practitioner to a health care facility to render temporary health care services in this State shall file an application with the Secretary, on a *written or electronic* form provided by the Secretary.

(2)—(3) (text unchanged)

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 by submitting a renewal application on a written or electronic form provided by the Secretary, if the agency:

(a)—(b) (text unchanged)

(3) (text unchanged)

E.-G. (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

.03 Licensing Procedure.

A. Application. Applicants shall conform to the following:

(1) An applicant desiring to open or to continue the operation of an existing center shall file with the Secretary, on a *written or electronic* form provided by the Secretary, a notarized application:

(a)—(c) (text unchanged)

(2)—(3) (text unchanged)

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

[(a) Copy of constitution and by-laws;

(b) List of officers and Board members with addresses;

(c) The operating budget for the current year;

(d) Copies of publicity;

(e) Statement of area, number, age, and sex of children to be served;

(f) Definition and description of service;

(g) Plan for medical, dental, psychological, and psychiatric service;

(h) An educational plan, that is, educational objectives and methodology;

(i) Personnel policies, including definition of jobs, qualifications, salaries, hours, vacation, sick leave, and retirement;

(j) Admission policies;]

[(k)](a)—[(l)](b) (text unchanged)

[(m) A procedure for providing services for the transfer of a resident to a suitable facility in the event of accident or development of other acute condition;]

(c) A current food service permit; and

[(n)] (d) Copy of signed agreement between the center and the principal *somatic* physician [including the name of the "relief"] *and psychiatrist.*

(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 *written or electronic* forms provided by the Secretary.

B.—C. (text unchanged)

D. Licenses for Less Than 12 Months for the Operation of Hospitals and Related Institutions.

[(1) Article 43, §559(b)(1), Annotated Code of Maryland, provides inter alia, that licenses to operate a hospital or related institution "be issued for a term not to exceed one year and shall be provisional in nature pursuant to rules and regulations..."]

[(2)] (1) Criteria for Issue. [Whenever a regular license cannot be issued, under conditions as set forth in these regulations,] *The Secretary may issue* a provisional license [may be issued], *pending accreditation by The Joint Commission, valid for a period not to exceed 12 months.* [In order to implement the statute, consideration for a provisional license to hospitals or related institutions will be based upon one of the following departmental regulations:

(a) When an institution has substantial deficiencies which, in the opinion of the Department, do not constitute a life-safety or health hazard but the institution is unable to correct by the scheduled license renewal date;

(b) When an institution has substantial deficiencies which, in the opinion of the Department, have no adverse effect on the life-safety or health status of patients but require construction or remodeling to correct and, the institution has a bona fide commitment to correct these deficiencies by a prescribed date;

(c) When Departmental administrative delays have occurred which are beyond the control of the hospital or related institution;

(d) When new construction is completed to the point of being able to provide all necessary services to its patients or residents, but certain substantial items of equipment or optional services, which in the opinion of the Department have no adverse effect on the safety or health of its patients or residents, are lacking temporarily.

(3) Duration of License.

(a) The licensing period for licenses of less than 12 months may vary from a minimum of 1 month to a maximum of 6 months.

(b) Only one license of less than 12 months will be issued during a given licensure period unless the institution can demonstrate that extenuating circumstances exist which are beyond the control of the institution in meeting a prescribed deadline, or unless it is necessary to allow the Department to coordinate and unify its annual licensing dates with federal certification dates. On this basis, a one-time renewal may be granted for a maximum period of 6 months.

(c) However, if it is demonstrated to the Department's satisfaction that whatever modifications are necessary to correct the deficiencies will take more than 1 year to complete, the Department may issue as many renewals as are necessary. Each renewal shall be approved by the Secretary.

E. Return of License to the Secretary. When the facility is sold, leased, discontinued, the operation moved to a new location, the license has been revoked, or its renewal denied, the license immediately becomes void and shall be returned to the Secretary.

F. Obligation of New Licensee. The new licensee, before taking over operation of an existing center or activating a new center shall obtain a license from the Secretary. The licensee shall conform to all currently applicable regulations.]

10.07.05 Residential Service Agencies

Authority: Health-General Article, Title 19, Subtitle 4A, Annotated Code of Maryland

.04 Licensing Procedures.

A. Application for License.

(1) (text unchanged)

(2) An applicant shall submit:

(a) An application on a *written or electronic* form developed by the Department;

(b)—(k) (text unchanged)

B.—H. (text unchanged)

I. License Renewal. A licensee shall submit to the Department:

(1) An application for license renewal on a written or electronic form developed by the Department;

(2)—(5) (text unchanged)

J.-K. (text unchanged)

10.07.07 Nursing Referral Service Agencies

Authority: Health-General Article, Title 19, Subtitle 4B, Annotated Code of Maryland

.04 Licensing Procedures.

A. Application for License.

(1) A person desiring to conduct, operate, or maintain a nursing referral service agency in this State shall file an application with the Secretary, on the *written or electronic* form provided by the Secretary.

(2)—(3) (text unchanged)

B.—D. (text unchanged)

E. License Renewal.

(1) The agency shall file an application for relicensure *on the written or electronic form provided by the Secretary* at least 60 days before the expiration of its current license.

(2) (text unchanged)

10.07.08 Freestanding Medical Facilities

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

.04 Licensing Application Procedure.

A. (text unchanged)

B. A hospital desiring to establish a freestanding medical facility shall apply to the Department for initial licensure on a *written or electronic* form provided by the Secretary.

C.—E. (text unchanged)

.05 Renewal of License.

A. A licensee shall file an application for license renewal with the Secretary on a *written or electronic* form provided by the Secretary.

B.--C. (text unchanged)

10.07.09 Residents' Bill of Rights: Comprehensive Care Facilities and Extended Care Facilities

Authority: Health-General Article, §19-344, Annotated Code of Maryland

.08 Resident's Rights and Services.

A.-B. (text unchanged)

- C. A resident has the right to:
 - (1)—(21) (text unchanged
 - (22) Visit privately with the resident's spouse or domestic partner;
 - (23)—(32) (text unchanged
- D.-F. (text unchanged)

10.07.10 Home Health Agencies

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

.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 *written or electronic* form provided by the Secretary.

C. Renewal of License. An agency shall file an application *on the written or electronic form provided by the Secretary* for renewal of the license at least 60 days before expiration of the issued license and submit it on forms provided by the Secretary.

D.-G. (text unchanged)

10.07.11 Health Maintenance Organizations

Authority: Health-General Article, §19-705.1, Annotated Code of Maryland

.04 Peer Review.

- A. (text unchanged)
- B. External Review.

(1)—(3) (text unchanged)

(4) The external review shall consist of a review and evaluation of the following:

(a)—(c) (text unchanged)

(d) The grievances relating specifically to the delivery of medical care, including their final disposition; *and* [(e) The physical facilities and equipment; and]

[(f)] (e) (text unchanged)

(5) (text unchanged)

.05 Medical Records.

[A. The HMO shall maintain an individual record for each patient according to accepted professional principles and the provisions of these regulations, with entries kept current, dated, and signed by a physician or other medical professional.]

[B.] A.--[H.] G. (text unchanged)

.09 Access and Availability of Services.

A. Regular Hours.

(1) With respect to all services it furnishes, whether direct or through contractual arrangements, an HMO shall provide for regular hours during which an enrollee may receive services. [It is also required to]

(2) An HMO that provides services directly to its enrollees through its staff members shall have an orderly system for scheduling the provision of services to enrollees in a timely manner, taking into account the immediacy of need for services.

(3) An HMO that provides services to its enrollees through independent licensed health care providers under contract with the HMO shall ensure that the providers have an orderly system for scheduling the provision of services to enrollees in a timely manner, taking into account the immediacy of need for services.

B. (text unchanged)

.10 Physician Availability.

A. The HMO shall have a physician available at all times to provide diagnostic and treatment services. The HMO shall assure that every enrollee seen for a medical complaint is evaluated under the direction of a physician and that every enrollee receiving diagnostic evaluation or treatment is under the direct medical management of an HMO physician *or certified nurse practitioner* who provides continuing medical management.

B. Each enrollee shall have an opportunity to select a primary physician *or certified nurse practitioner* from among those available to the HMO.

10.07.12 Health Care Facilities Within Correctional Institutions

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

.04 License Procedure.

Applicants for licensure shall conform to the following:

A. Any person desiring to open and operate a health care facility within a correctional institution or to continue the operation of an existing health care facility, shall file [an] *a written or electronic* application with the Department giving the information required by the [Division of Licensing and Certification] *Office of Health Care Quality*;

B. (text unchanged)

.20 Dietary Services.

A. Adequacy of Diet.

[(1)] (text unchanged)

[(2) To the extent medically possible, the current recommended Dietary Allowance of the Food and Nutrition Board of the National Research Council, adjusted for age, sex, and activity, shall be observed.]

B.—F. (text unchanged)

10.07.14 Assisted Living Programs

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

.07 Licensing Procedure.

- A. Application for License.
 - (1) (text unchanged)
 - (2) An applicant shall submit:
 - (a) An application on a *written or electronic* form developed by the Department;

(b)—(c) (text unchanged)

(3)—(5) (text unchanged)

B. (text unchanged)

C. Duration of License.

(1) (text unchanged)

(2) License Renewal. A licensee shall apply for license renewal:

(a) (text unchanged);

(b) On written or electronic forms provided by the Department; and

(c) (text unchanged)

D. (text unchanged)

10.07.16 Limited Private Inpatient Facilities

Authority: Health-General Article, §§10-501-10-511, Annotated Code of Maryland

.05 Licensure Process.

A. (text unchanged)

B. Initial and Renewal Licensure. In order to be licensed as a limited private inpatient facility, the facility shall:

(1) File an initial application with the Department that:

(a) Is on the *written or electronic* form approved by the Department with the requirement that all questions are answered and all required documents are attached; and

(b) (text unchanged)

(2)—(4) (text unchanged)

C.-F. (text unchanged)

G. Renewal of License.

(1) An application *on the written or electronic form provided by the Department* for the renewal of the license shall be made by an accredited facility within 30 calendar days of the exit date of the triennial survey conducted by the Joint Commission.

(2) (text unchanged)

H. (text unchanged)

I. License Fees.

(1) A facility shall submit [an] *a written or electronic* application *on a form approved by the Department* along with the fee established in this regulation.

(2)—(3) (text unchanged)

J. (text unchanged)

10.07.17 Limited Service Hospital

Authority: Health-General Article, §§19-308 and 19-319, Annotated Code of Maryland

.03 Application Procedure.

A. A person desiring to convert an existing facility, or to change the classification of an existing hospital to a limited service hospital, shall file an application with the Secretary, on a *written or electronic* form provided by the Secretary. B.—E. (text unchanged)

D. D. (text unentanget

.04 License Renewal.

A. The licensee shall file an application for license renewal *on a written or electronic form provided by the Secretary* at least 60 days before the current license expires.

B. (text unchanged)

10.07.18 Comprehensive Rehabilitation Facilities

Authority: Health-General Article, §19-1203, Annotated Code of Maryland

.04 License Provisions.

A. (text unchanged)

B. To obtain a comprehensive rehabilitation facility license, a person shall:

(1) Submit an application on the *written or electronic* form provided by the Secretary;

(2)—(3) (text unchanged)

C.—D. (text unchanged)

E. An application for the renewal of the license shall be made *on the written or electronic form provided by the Secretary* at least 60 days before expiration of the issued license.

F. (text unchanged)

10.07.20 Intermediate Care Facilities for Individuals with Intellectual Disabilities and Persons with Related Conditions (ICF/IID)

Authority: Health-General Article, §19-318, Annotated Code of Maryland

.04 Licensing Procedure.

- A. (text unchanged)
- B. An applicant for a license shall:
 - (1) Submit to the Secretary an application:

(a) In the form and manner prescribed by the Secretary *on the written or electronic form provided by the Secretary*; and

(b) Signed and verified by the applicant; and

(2) (text unchanged)

C.-D. (text unchanged)

E. Term and Renewal of License.

(1) (text unchanged)

(2) Before the license expires, the licensee may renew it for another 1-year term, if the licensee submits to the Secretary:

(a) A renewal application in the form and manner prescribed by the Secretary *on the written or electronic form provided by the Secretary*;

(b)—(c) (text unchanged)

F. (text unchanged)

10.07.21 Hospice Care Programs

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

.04 Application Procedure.

A. (text unchanged)

B. The applicant shall submit an application for an initial license or renewal of a license on a *written or electronic* form provided by the Secretary.

C.-E. (text unchanged)

Subtitle 10 LABORATORIES

10.10.03 Medical Laboratories — Licenses

Authority: Health-General Article, §§17-202 and 17-205, Annotated Code of Maryland

.02 Letters of Exception.

A. (text unchanged)

B. Excepted Tests. A POL or POCL operating under a letter of exception may perform one or more of the following excepted tests or types of tests:

(1)—(34) (text unchanged)

(35) CLIA waived blood lipid analysis for cholesterol, HDL, LDL, and triglycerides; [and]

(36) Whole blood lead testing on a CLIA waived analyzer with the additional requirements: (a)—(d) (text unchanged)

(e) Reporting requirements stated in §C of this regulation shall be followed; and

(37) CLIA Waived Urine Drug Screens with the following additional requirements:

(a) The licensee shall enroll into a proficiency testing program offered by an entity that has been approved by the Centers for Medicare and Medicaid Services; and

(b) When the numerical score is less than 80 percent, the licensee shall submit the official proficiency test result to the Office of Health Care Quality for review and monitoring with evidence of documented remedial actions taken.

C.—D. (text unchanged)

Subtitle 21 MENTAL HYGIENE REGULATIONS

10.21.16 Community Mental Health Programs — Application, Approval, and Disciplinary Processes

Authority: Health-General Article, §7.5-205, Annotated Code of Maryland

.04 Application Process.

A.-B (text unchanged)

C. Application. An applicant for approval of a program shall:

(1) Submit an application to the Department's designated approval unit;

(2) Submit the application on the *written or electronic* form approved by the Department, with all questions answered and all required documents attached;

(3)—(4) (text unchanged)

D.—F. (text unchanged)

Subtitle 22 DEVELOPMENTAL DISABILITIES

10.22.02 Administrative Requirements for Licensees

Authority: Health-General Article, §7-904, Annotated Code of Maryland

.02 Application for Initial License or Renewal.

A. (text unchanged)

B. An applicant shall file an application for a license or license renewal on a *written or electronic* form provided by the Administration. An existing licensee shall file an application for renewal at least 60 days before expiration of its existing license. The license does not expire until the Director takes an action under §D of this regulation and the time for seeking judicial review or any judicial stay of the final action expires.

C.—F. (text unchanged)

Subtitle 47 ALCOHOL AND DRUG ABUSE ADMINISTRATION

10.47.04 Certification Requirements

Authority: Health-General Article, §7.5-205, Annotated Code of Maryland

.04 Type and Duration of Certification.

A. Initial Certification.

(1) After receipt of the completed *written or electronic* application *provided by the Administration* and *after* inspection by the Office of Health Care Quality, if there are no deficiencies, the Administration shall grant an initial certification.

(2) The initial certification is valid for a period in the discretion of the Administration, not to exceed 6 months. B. Provisional Certification.

(1) (text unchanged)

(2) If upon review of a *written or electronic* renewal application *provided by the Administration*, the Office of Health Care Quality finds deficiencies which are not life threatening, the Administration may grant a provisional certification to permit the program to correct the deficiencies as set forth in the plan of correction.

(3) (text unchanged)

C.—D. (text unchanged)

.05 Application Process and Evaluation.

A. Application. An applicant for certification of a program or renewal of certification shall submit to the Office of Health Care Quality:

(1) A completed application on a *written or electronic* form approved by the Administration;

(2)—(4) (text unchanged)

B.—E. (text unchanged)

Subtitle 51 FORENSIC LABORATORIES

10.51.03 Licenses

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

.02 License — Requirements.

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

(1) Obtain, complete, and submit *written or electronic* permit applications as prescribed in this subtitle; (2)—(3) (text unchanged)

B. (text unchanged)

.03 License — Administrative Procedures.

A. Application — Filing.

(1) A person shall:

(a) (text unchanged)

(b) File an application for a license using written or electronic forms provided by the Department; and

(c) (text unchanged)

(2) (text unchanged) B.—E. (text unchanged)

F. Expiration and Renewal.

(1)—(2) (text unchanged)

(3) In order to renew a license, a licensee shall file an application to renew the license using *written or electronic* forms provided by the Department and following the same procedures prescribed in §§A and B of this regulation.

(4) (text unchanged) G.—H. (text unchanged)

> VAN T. MITCHELL Secretary of Health and Mental Hygiene