Exhibit 2

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Title 10

MARYLAND DEPARTMENT OF HEALTH

Subtitle 24 MARYLAND HEALTH CARE COMMISSION

10.24.01 Procedural Regulations for Health Care Facilities and Services

Authority: Health-General Article, §§19-109(a)(1), 19-118(d), 19-120, 19-120.1, and 19-126, et seq., Annotated Code of Maryland

.01 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Acquisition" means:

(a) Any transfer of stock or assets that results in a change of the person or persons who control a health care facility; or

(b) The transfer of any stock or ownership interest in excess of 25 percent.

(2) "Adversely affected", for purposes of determining interested party status in a Certificate of Need review, as defined in §B(35) of this regulation, means that a person:

(a) Is authorized to provide the same service as the applicant, in the same planning region, or contiguous planning region if the proposed new facility or service could reasonably provide services to residents in the contiguous area, and can demonstrate that the approval of the application:

(i) Would materially affect the quality of care at a health care facility that the person operates, such as by causing a reduction in the volume of services when volume is linked to maintaining quality of care; or

(ii) Would result in a substantial depletion of essential personnel or other resources at a health care facility that the person operates; or

(b) Can demonstrate to the reviewer that a health care facility operated by the person could suffer a potentially detrimental impact from the approval of a project before the Commission, in

an issue area over which the Commission has jurisdiction, such that the reviewer, in the reviewer's sole discretion, determines that the person should be qualified as an interested party in the review.

(3) "Aggrieved party" means:

(a) An applicant or interested party who has submitted written exceptions to a proposed decision to the Commission and would be adversely affected by the final decision of the Commission; or

(b) The Secretary.

(4) Ambulatory Surgery Center.

(a) "Ambulatory surgery center" or "ASC" means any center, service, office, facility, or office of one or more health care practitioners, a group practice, or a non-rate-regulated center owned by a hospital that:

(i) Has no more than two operating rooms;

(ii) Operates primarily for the purpose of providing surgical services to patients who do not require overnight hospitalization; and

(iii) Seeks reimbursement from payors for the provision of ambulatory surgical services.

(b) "Ambulatory surgery center" or "ASC" includes the following subcategories:

(i) An ASC-P, which has only procedure rooms;

(ii) An ASC-1, which has one operating room; and

(iii) An ASC-2, which has two operating rooms.

(5) "Ambulatory surgical facility" means any center, service, office, facility, or office of one or more health care practitioners or a group practice that:

(a) Has three or more operating rooms;

(b) Operates primarily for the purpose of providing surgical services to patients who do not require overnight hospitalization; and

(c) Seeks reimbursement from a third-party payor as an ambulatory surgical facility.

(6) "Approved bed" means a bed approved by the Commission in a Certificate of Need, but not yet licensed.

(7) "Bed capacity" or "physical bed capacity" means the total number of beds that a health care facility can set up and staff in space designed for and licensable for use by patients requiring an overnight stay at the facility.

(8) “By or on behalf of” includes a capital expenditure that affects the physical plant, service volume, or service capacity of a health care facility or health maintenance organization regardless of the source of the funds.

(9) “Capital expenditure” means:

(a) An expenditure, including predevelopment costs, which:

(i) Is made as part of an acquisition, improvement, expansion, or physical plant replacement;

(ii) Results in a change or relocation that would require a CON under Regulation .02A(2)—(4) of this chapter; and

(iii) Is made by or on behalf of a health care facility that under generally accepted accounting principles is not properly chargeable as an expense of operation and maintenance or is made to obtain any physical plant for a facility by lease or comparable arrangement;

(b) A donation of a physical plant to a health care facility, if a Certificate of Need would be required for an expenditure by the health care facility to acquire the physical plant directly; or

(c) A transfer of a physical plant to a facility for less than fair market value, if the transfer of the physical plant at fair market value would be a capital expenditure.

(10) “Center for Health Care Facilities Planning and Development” means that center in the Commission that acts as the entry and information point for applications for Certificate of Need, requests for an exemption from Certificate of Need review, or other health care facility-related matters requiring action by the Commission, or its staff, as provided in this chapter.

(11) “Certificate of Conformance” means an approval issued by the Commission under Health-General Article, §19-120.1, Annotated Code of Maryland, that allows an acute general hospital to establish emergency percutaneous coronary intervention (PCI) services or elective PCI services without a Certificate of Need.

(12) “Certificate of Need” or “CON” means a certification of public need issued by the Commission under Health-General Article, Title 19, Subtitle 1, Annotated Code of Maryland.

(13) “Certificate of Ongoing Performance” means an approval issued by the Commission that the cardiac surgery services, emergency PCI services, or elective PCI services provided by an acute general hospital meet standards evidencing continued quality under Health-General Article, §19-120.1, Annotated Code of Maryland.

(14) “Commission” means the Maryland Health Care Commission.

(15) “Comparable” when used to determine whether two or more CON applications are subject to comparative review means that the proposed projects are in the same health planning region and involve the addition or expansion of at least one of the same medical services.

(16) “Comparative review” means a review in which two or more comparable CON applications are reviewed together and ranked based on each application’s satisfaction of the CON review criteria because the most recently published need projections do not support the implementation of all comparable projects.

(17) “CON-approved service” means any health care service for which a CON was obtained, including:

(a) Medical services;

(b) Cardiac surgery services;

(c) Organ transplant services;

(d) Burn treatment services; and

(e) Neonatal intensive care services.

(18) “Consolidation” means the reconfiguration of two or more health care facilities within a merged asset system such that:

(a) The health care facilities in the merged asset system are combined and the total number of health care facilities of the merged asset system is reduced; or

(b) The medical services or bed capacity are reallocated among two or more health care facilities of the merged asset system.

(19) “Contested review” means a review in which a person has been recognized as an interested party.

(20) “Department” means the Maryland Department of Health.

(21) “Determination of coverage” means the written determination in accordance with Regulation .14A of this chapter whether CON or other Commission review is required for a project.

(22) “Executive Director” means the person appointed chief administrative officer of the Commission in accordance with Health-General Article, §19-106, Annotated Code of Maryland.

(23) “Existing health care facility” means a health care facility that is licensed by the Department.

(24) “Freestanding medical facility” has the meaning stated in Health-General Article, §19-3A-01, Annotated Code of Maryland.

(25) “General hospice care program” has the meaning stated in Health-General Article, §l9-901, Annotated Code of Maryland.

(26) Health Care Facility.

(a) “Health care facility” means:

(i) A hospital, as defined in Health-General Article, §19-301, Annotated Code of Maryland;

(ii) A limited service hospital, as defined in Health-General Article, §19-301, Annotated Code of Maryland;

(iii) A related institution, as defined in Health-General Article, §19-301, Annotated Code of Maryland;

(iv) An ambulatory surgical facility;

(v) An inpatient facility that is organized primarily to help in the rehabilitation of disabled individuals, through an integrated program of medical and other services provided under competent professional supervision;

(vi) A home health agency, as defined in Health-General Article, §19-401, Annotated Code of Maryland;

(vii) A hospice, as defined in Health-General Article, §19-901, Annotated Code of Maryland;

(viii) A freestanding medical facility, as defined in Health-General Article, §19-3A-01, Annotated Code of Maryland;

(ix) A comprehensive care facility, except as provided by Regulation .03 of this chapter and Health-General Article, §19-114(d)(2), Annotated Code of Maryland; and

(x) Other health institutions, services, or programs that may be specified as requiring a CON under State law.

(b) “Health care facility” does not mean:

(i) A hospital or related institution operated, or listed and certified, by the First Church of Christ Scientist, Boston, Massachusetts;

(ii) A kidney disease treatment facility, or the kidney disease treatment stations and services provided by or on behalf of a hospital, if the facility or the services do not include kidney transplant services or programs; or

(iii) The office of one or more individuals licensed to practice dentistry under Health Occupations Article, Title 4, Annotated Code of Maryland, for the purposes of practicing dentistry.

(27) "Health care project" means a health care project requiring a Certificate of Need as set forth in Regulation .02 of this chapter.

(28) "Health care services" means clinically-related patient services, including medical services.

(29) "Health maintenance organization" or "HMO" means a health maintenance organization under Health-General Article, §19-701, Annotated Code of Maryland.

(30) "Health planning region" means the area used for regulation of a particular service as provided in the State Health Plan.

(31) "Holder" means the applicant or applicants to whom the Commission awarded a Certificate of Need, an exemption from Certificate of Need, or other Commission approval for a project that has not received first use approval or, if necessary, a license from the Department for that project.

(32) Home Health Agency.

(a) "Home health agency" has the meaning stated in Health-General Article, §19-401(b), Annotated Code of Maryland.

(b) "Home health agency" includes a parent home health agency, as defined by the Centers for Medicare and Medicaid Services under 42 CFR §484.2.

(33) "Hospital capital threshold" has the meaning stated in Health-General Article, §19-120(a)(4), Annotated Code of Maryland.

(34) "Initiation of construction" means:

(a) For a new health care facility or expansion of an existing health care facility, that an approved project has:

(i) Obtained all permits and approvals considered necessary by applicable federal, State, and local authorities to initiate construction;

(ii) Completed all necessary preconstruction site work; and

(iii) Started the installation of the foundation system with placement of permanent components such as reinforcing steel, concrete, and piles; and

(b) For the renovation of an existing health care facility, that an approved project has:

(i) Obtained all permits and approvals considered necessary by applicable federal, State, and local authorities to initiate renovation; and

(ii) Started the demolition or relocation of affected services necessary to undertake the renovation project.

(35) "Interested party" means a person recognized by a reviewer as an interested party, including:

(a) Any applicant who has submitted a competing application in a comparative review;

(b) The staff of the Commission;

(c) A local health department in the jurisdiction or, in the case of regional services, in the planning region, in which the proposed facility or service is to be offered;

(d) In the review of a replacement acute general hospital project proposed by or on behalf of a regional health system that serves multiple contiguous jurisdictions, a jurisdiction within the region served by the regional health system that does not contain the proposed replacement acute general hospital project; and

(e) A person who has demonstrated to the reviewer that it meets the definition of adversely affected by the approval of a proposed project.

(36) "Intermediate care" means:

(a) A planned regimen of 24-hour professional directed evaluation, observation, medical monitoring, and addiction treatment in an inpatient setting for individuals with substance abuse disorder, including American Society of Addiction Medicine (ASAM) Level 3.7 medically monitored intensive inpatient services; and

(b) Residential care, treatment, or custody of individuals with intellectual disability or persons with related conditions.

(37) "Jurisdiction" means the 23 counties of Maryland and Baltimore City.

(38) Licensed Bed Capacity.

(a) "Licensed bed capacity" means the number of health care facility beds in any of the medical service categories or subcategories, as they appear in the Commission's inventories of licensed service capacity.

(b) “Licensed bed capacity” for acute general hospitals:

(i) Means the capacity authorized by the Secretary under Health-General Article, §19-307.2, Annotated Code of Maryland;

(ii) Does not mean the number of holding beds to support hospital emergency services, bassinets, beds dedicated to observation of patients, an outpatient service, or recovery beds to support ambulatory surgical services.

(39) “Limited service hospital” means a health care facility that:

(a) Is licensed as a hospital;

(b) Changes the type or scope of health care services offered by eliminating the facility's capability to admit or retain patients for overnight hospitalization;

(c) Retains an emergency or urgent care center; and

(d) Complies with the regulations adopted by the Secretary under Health-General Article, §19-307.1, Annotated Code of Maryland.

(40) “Local health department” means the health department in a jurisdiction or a body designated by that jurisdiction to perform health planning functions.

(41) “Long-term significant relationship” means a relationship characterized by mutual economic dependence, demonstrated by evidence such as a joint lease or mortgage or power of attorney, and evidence of common legal residence shown by driver's licenses, voter registration, or other identification.

(42) “Maryland Health Care Commission” means the agency established by Health-General Article, Title 19, Subtitle 1, Annotated Code of Maryland.

(43) “Medical service” means:

(a) Any of the following categories of health care services as they appear in the Commission's inventories of service capacity:

(i) Medical/surgical/gynecological/addictions;

(ii) Obstetrics;

(iii) Pediatrics;

(iv) Psychiatry;

(v) Rehabilitation;

(vi) Chronic care;

(vii) Comprehensive care;

(viii) Extended care;

(ix) Intermediate care; or

(x) Residential treatment center care; or

(b) A subcategory of the rehabilitation, psychiatry, comprehensive care, or intermediate care categories of medical services for which the State Health Plan provides a need projection methodology or specific standards.

(44) "Merged asset system" means an organization~~entity~~ comprised of one or more regulated health care facilities under common ownership or control.

(45) "Merger" means the union of two or more health care facilities by the transfer of all the property of one or more of them to one of them, which continues in existence, the others being merged therein.

(46) "Multiphased plan of construction" means a plan of construction for an addition, replacement, modernization, relocation, or conversion of an existing health care facility that involves distinct elements of construction, demolition, or renovation that require sequential implementation such that one element can be initiated before subsequent elements of the overall project can be initiated.

(47) "Operating room" means a sterile room in a surgical suite that meets the requirements of a restricted area and is designated and equipped for performing surgical operations or other invasive procedures that require an aseptic field.

(48) "Other Commission approval" means approval of a Certificate of Conformance, Certificate of Ongoing Performance, or an exemption from CON review.

(49) "Partial closing" or "partial closure" means the closure or decommission of one or more but not all CON-approved services offered by a health care facility.

(50) "Participating entity" means a person recognized by the Executive Director as a participating entity and may include:

(a) A third-party payor including:

(i) An insurer or nonprofit health service plan that holds a certificate of authority and provides health insurance policies or contracts in Maryland;

(ii) A health maintenance organization that holds a certificate of authority in Maryland;

(iii) A union that is providing a health plan to union members on behalf of an employer in a jurisdiction in which the proposed project will be located or from which an existing health care facility seeks to relocate;

(iv) A pharmacy benefit manager; and

(v) A self-insured employer offering health benefits through the Employer Retirement Insurance Security Act of 1974;

(b) A municipality where the proposed project will be located or from which an existing health care facility seeks to relocate; or

(c) In the case of a hospital project, a local health department in a jurisdiction that borders a jurisdiction in which a proposed facility or service will be located.

(51) "Person" includes an individual, receiver, trustee, guardian, executor, administrator, fiduciary, or representative of any kind and any partnership, firm, association, limited liability company, limited liability partnership, public or private corporation, or other entity.

(52) Personal Physician.

(a) "Personal physician" means a physician licensed to practice medicine who:

(i) Was chosen by an individual;

(ii) Has an established physician-patient relationship with the individual; and

(iii) Has provided health care services to the individual.

(b) "Personal physician" does not mean an owner of, an employee of, a person under contract with, or a person who has a material financial interest in a continuing care retirement community, its management company, or related entity.

(53) Predevelopment Costs.

(a) "Predevelopment costs" means all costs related to the preliminary development of a project, which include, but are not limited to, the costs of preliminary plans, studies, surveys, architectural designs, plans, reports, application fees, legal fees, financing fees, consulting fees, working drawings, or specifications undertaken in preparation for the development or offering of a health care project.

(b) "Predevelopment costs" does not include activities routinely undertaken by a health care facility as a part of its internal management or long-range planning process.

(54) "Primary service area" means:

(a) The Maryland postal ZIP code areas from which the first 60 percent of a hospital's patient discharges originate during the most recent 12-month period, where:

(i) The discharges from each ZIP code area are ordered from largest to smallest number of discharges; and

(ii) Two or more ZIP code areas having the same numbers of discharges are ordered from the largest to smallest based on the percentage of the hospital's discharges originating from the ZIP code area in the most recent 12-month period;

(b) Point ZIP codes physically within any of the ZIP code areas designated in §B(54) of this regulation;

(c) Maryland ZIP code areas physically contiguous to any of the ZIP codes designated in §B(54) of this regulation that provided 50 percent or more of their discharges to the hospital in the most recent 12-month period; and

(d) For a merged asset system, the ZIP code areas that are tabulated separately for each hospital, and all ZIP code areas identified for each hospital which are included in the primary service area of the merged asset system.

(55) Public Obligation.

(a) "Public obligation" means a bond, note, evidence of indebtedness, or other obligation to repay borrowed money issued by:

(i) The Maryland Health and Higher Educational Facilities Authority;

(ii) The State, or any agency, instrumentality, or public corporation of the State;

(iii) A governmental entity described in Local Government Article, §19-205(a), Annotated Code of Maryland;

(iv) The Mayor and City Council of Baltimore; or

(v) A municipal corporation.

(b) "Public obligation" does not include an obligation, or portion of an obligation, if:

(i) The principal of and interest on the obligation or the portion of the obligation is insured by an effective municipal bond insurance policy and issued on behalf of a hospital that voluntarily closed in accordance with Health-General Article, §19-120(l); and

(ii) The proceeds of the obligation or the portion of the obligation are used to finance wholly or partly a facility or part of a facility that is used primarily to provide outpatient services

at a location other than the hospital or that is used primarily by physicians who are not employees of the hospital to provide services to nonhospital patients.

(56) "Regional health system" means a hospital whose primary or secondary service area cover multiple jurisdictions.

(57) "Rehabilitation facility" means an inpatient facility that:

(a) Is organized for the primary purpose of assisting in the rehabilitation of persons with disabilities through an integrated program of medical and other services, which are provided under competent professional supervision;

(b) Is licensed as a special rehabilitation hospital; and

(c) Complies with the regulations adopted by the Secretary under Health-General Article, Title 19, Subtitle 3, Annotated Code of Maryland.

(58) "Religious order" means an incorporated, not-for-profit organization:

(a) That is owned or is wholly operated by an entity founded and operating for the sole purpose of carrying out religious precepts; and

(b) Whose members have taken the vows required by the order and have devoted their lives to religious service, to the exclusion of lay life and activities.

(59) "Residential treatment center" has the meaning stated in Health-General Article, §19-301(p), Annotated Code of Maryland.

(60) "Reviewer" means one Commissioner, appointed by the Executive Director of the Commission, who:

(a) Evaluates a Certificate of Need application;

(b) Prepares a proposed decision for the consideration of the full Commission; and

(c) Serves as presiding officer at an evidentiary hearing on an application or applications, if any.

(61) "Secretary" means the Secretary of Health.

(62) "Service area" means the geographic area from which a health care facility or provider draws its patients. Unless otherwise specified in a relevant State Health Plan chapter, service area means the zip code areas from which the greatest number of patients reside, which, when ordered from largest to smallest, comprise the top 85 percent of patients who receive a specific service at a health care facility for the most recent 12-month period of data available.

(63) “State Health Plan” means the State Health Plan for Facilities and Services and its modifications or additions, adopted by the Commission pursuant to Health-General Article, §19-118, Annotated Code of Maryland.

.02 Coverage.

A. Except as provided in Regulations .03—.05 of this chapter or as otherwise provided by law, a CON is required before:

(1) A new health care facility is built, developed, or established;

(2) An existing health care facility is moved to another site, unless the relocation is:

(a) The result of a partial or complete replacement of an existing hospital or related institution, as defined in Health-General Article, §19-301, Annotated Code of Maryland, and is to another part of the site or immediately adjacent to the site of the existing hospital or related institution;

(b) Of an existing health care facility owned or controlled by a merged asset system, subject to the provisions of Regulations .03E or .04A(2) of this chapter, whichever is applicable; or

(c) By a hospital converting to a limited service hospital, subject to the provisions of Regulation .04A(4) of this chapter, and is to a site within the immediate area, as determined by the Commission, as described in §B of this regulation;

(3) The bed capacity of a health care facility is changed;

(4) The type or scope of any health care service offered by a health care facility is changed, and the change:

(a) Establishes a new medical service;

(b) Establishes a new cardiac surgery, organ transplant surgery, burn treatment, or neonatal intensive care program;

(c) Establishes a new home health agency, general hospice care program, or ambulatory surgical facility;

(d) Builds or expands surgical capacity in a hospital, freestanding medical facility subject to rate regulation by the Health Services Cost Review Commission, or ambulatory surgical facility;

(e) Results in:

(i) The establishment of a new parent home health agency; or

(ii) The expansion of an existing home health agency into a jurisdiction in which it was not previously authorized by the Commission to operate;

(f) Eliminates an existing medical service; or

(g) Closes an existing health care facility or converts it to a non-health-related use; or

(5) A hospital makes a capital expenditure, as defined in Health-General Article, §19-120(k), Annotated Code of Maryland, and in this chapter, that exceeds the hospital capital threshold, including a capital expenditure:

(a) For the relocation of an existing health care facility owned or controlled by a merged asset system, except as provided in Regulation .03E of this chapter; and

(b) By a relocated health care facility to permit the facility to offer a new health care service for which CON is otherwise required.

B. Definition of Immediate Area for Limited Service Hospital Conversion.

(1) For the purpose of §A(2)(c) of this regulation, "immediate area" means a location on the site of the existing hospital, or on an adjacent site.

(2) A hospital may provide evidence as to why the Commission should approve a site for a limited service hospital beyond the immediate area of the converting hospital.

(3) The Commission may not approve a site for a limited service hospital unless the site is within:

(a) A 5-mile radius of the site of the hospital proposing the conversion; and

(b) Its primary service area.

C. A person may not divide a project into component parts except as permitted by this chapter. Commission staff shall issue a determination regarding whether two or more apparently individual projects actually represent component parts of a single project, considering, among other things, the timing of the projects, the functional areas of a facility to be affected, the number of construction contracts entered into, and whether expenditures under one contract depend upon the completion of a prior contract.

D. Proposed Change After Acquisition. If a person acquires an existing health care facility or service without a CON, in accordance with Regulation .03 of this chapter, and proposes to change the health care services it provides or its bed capacity, the proposed change requires review and approval in accordance with §A of this regulation.

E. A health maintenance organization, or health care facility that either controls, directly or indirectly, or is controlled by an HMO or a group of HMOs, shall obtain a CON before it builds, develops, operates, or participates in building, developing, or operating:

(1) A hospital; or

(2) Any other health care project for which a CON is required under §A of this regulation, unless at least 90 percent of the patients who will receive health care services from the project will be individuals enrolled in that health maintenance organization.

F. If a person is uncertain whether a project requires a Certificate of Need, the person shall request a determination of coverage in accordance with Regulation .14A of this chapter.

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.03 Non-Coverage by Certificate of Need or Other Commission Approval.

A. Acquisition of an Existing Health Care Facility.

(1) At least 30 days before closing on a contract to acquire a health care facility, the person acquiring the facility shall notify the Commission in writing, with a copy to the local health officer in each affected jurisdiction and the appropriate State licensing agency, of the intent to acquire the facility, and include the following information:

(a) The health care services provided by the facility;

(b) The bed capacity, or jurisdiction served, if a community-based service;

(c) Complete organizational charts that describe the ownership of the health care facility prior to and after the proposed acquisition; and

(d) Any other information required by this chapter, by the State Health Plan chapter applicable to the health care facility, or requested by Commission staff.

(2) Deemed Approval.

(a) Except for acquisitions of a comprehensive care facility established under §I of this regulation, CON review is not required if Commission staff does not issue either a determination of coverage or notice that timely or complete notice was not received within 60 days of receipt of a notice from the person acquiring the health care facility.

(b) Upon request, Commission staff shall provide written confirmation that an acquisition was deemed approved under this regulation.

(3) Commission staff's determination that CON or other Commission review is not required remains valid for 180 days from its issuance. A new determination of coverage shall be required if the acquisition is not completed within that time period.

(4) If the acquisition is completed, the buyer shall sign a notice of completion of acquisition and file it with the Commission within 15 days of the completion of the acquisition.

B. Acquisition of a Comprehensive Care Facility, Home Health Agency, or Hospice.

(1) In addition to providing the information required in §A of this regulation, a person seeking to acquire a comprehensive care facility, home health agency, or hospice shall:

(a) Identify each person with an ownership interest in the acquiring entity or a related or affiliated entity, including

(i) The percentage of ownership interest of each such person; and

(ii) The history of each such person's experience in ownership or operation of health care facilities;

(b) Provide information on corporate structure and affiliations of the acquirer, purchase price, source of funds, and other relevant data as requested;

(c) Affirm that the services provided will not change as a result of the proposed acquisition and that its commitment to Medicaid participation, if any, will not decrease as a result of the proposed acquisition; and

(d) Affirm under penalties of perjury, that within the last 10 years no owner or former owner of the purchaser, or member of senior management or management organization, or a current or former owner or senior manager of any related or affiliated entity has been convicted of a felony or crime, or pleaded guilty, nolo contendere, entered a best interest plea of guilty, received a diversionary disposition regarding a felony or crime, and that the purchaser or a related or affiliated entity has not paid a civil penalty in excess of $10 million dollars that relates to the ownership or management of a health care facility.

(2) Disqualification for Acquisition. A comprehensive care facility, home health agency, or hospice may not be acquired by an entity if an owner or member of senior management or an owner or member of senior management of a related or affiliated entity of the acquiring entity has been convicted of a felony or crime or pleaded guilty, nolo contendere, entered a best interest plea of guilty, or received a diversionary disposition regarding a felony or crime within the last 10 years, unless:

(a) All of the individuals involved in the fraud or abuse are no longer associated with the entity or any of its related or affiliated entities;

(b) Each entity has fully complied with each applicable plan of correction; and

(c) If applicable, each entity has fully complied with each condition of the imposition of a civil penalty or agreed disposition.

(3) In an acquisition of a home health agency or hospice, the purchaser may only acquire the authority to provide services in jurisdictions for which the facility being acquired was granted a CON or is otherwise recognized by the Commission as having legal authorization.

C. Closure of a Health Care Facility.

(1) A CON is not required to close a health care facility or part of a health care facility, including a State hospital, if it provides notice to the Commission at least 90 days prior to the closing or 45 days prior to the partial closing and complies with the provisions of §C(2)—(4) of this regulation, if applicable.

(2) An acute general hospital shall hold a public informational hearing in accordance with Regulation .04D of this chapter if the hospital:

(a) Files a notice of the proposed closing of the hospital with the Commission; or

(b) Is located in a jurisdiction with fewer than three acute general hospitals and files a notice of the partial closing of the hospital.

(3) The Commission may require a health care facility not covered by §C(2) of this regulation to hold a public information hearing in accordance with Regulation .04D of this chapter.

(4) If a hospital that intends to close has outstanding public obligations issued on its behalf, written notice of its intended closing shall be given to the Maryland Health and Higher Educational Facilities Authority and the Health Services Cost Review Commission by the:

(a) Commission, within 5 days after receiving a written notification by the hospital of its intended closure;

(b) Hospital, within 10 days of filing with the Commission its written notification of its intended closure, along with a written statement of all public obligations issued on behalf of the hospital that provides the information required by Economic Development Article, §10-346(a)(2), Annotated Code of Maryland; and

(c) Commission, that the hospital held a public informational hearing in consultation with the Commission in the jurisdiction where the hospital is located.

D. Temporary Delicensure or Suspension of Bed Capacity, Health Care Facility, or CON-Approved Service.

(1) A temporary delicensure of licensed bed capacity or a licensed and operating health care facility or a temporary suspension of a CON-approved service does not require CON review, and the Commission will retain the bed capacity or health care facility on its inventory or permit the

reimplementation of the CON-approved service without obtaining a CON for up to 1 year, if the owner or licensed operator:

(a) Provides written notice to the Commission at least 30 days before the proposed temporary delicensure or temporary service suspension;

(b) Identifies good cause for the proposed temporary delicensure or temporary service suspension;

(c) States the intention either to bring the bed capacity back onto the facility's license or relicense the health care facility or reimplement the CON-approved service at the end of the 1-year period, or to notify the Commission that it intends to take another of the actions permitted under this subsection; and

(d) Has received authorization from the Executive Director for the temporary delicensure or temporary service suspension.

(2) Bed capacity or a facility that has been authorized by the Commission to be temporarily delicensed or a CON-approved service that has been authorized by the Commission to be temporarily suspended is not subject to the provisions of this section:

(a) During the pendency at the Commission of a letter of intent to apply or an application for CON approval involving the temporarily delicensed bed capacity or facility or the temporarily suspended CON-approved service;

(b) If the Commission has issued a Certificate of Need to reimplement the facility's temporarily delicensed bed capacity or the facility’s temporarily suspended CON-approved service;

(c) If the Commission has approved a request pursuant to Regulation .03 or .04 of this chapter to reimplement the bed capacity, facility or CON-approved service, and has determined that the bed capacity, facility, or CON-approved service may be reimplemented without a CON or other Commission approval, including but not limited to actions that may be undertaken by a merged asset system of which the facility is a member;

(d) If the Commission receives a notice of acquisition of the temporarily delicensed bed capacity or facility and the buyer and seller timely complete the acquisition, in accordance with Regulation .03 of this chapter; or

(e) If the Commission receives written notification that the owner or operator of the temporarily delicensed bed capacity or facility has applied for relicensure or reimplementation of the temporarily suspended CON-approved service.

(3) The requirements and procedures in this subsection do not apply to:

(a) A proposal to close, on either a temporary or a permanent basis:

(i) An acute general hospital or part of a hospital, including a medical service, in a jurisdiction with fewer than three acute general hospitals; or

(ii) A health care facility that provides any medical service approved by the Commission as a regional or Statewide health resource; or

(b) A temporary interruption of a CON-approved service that does not exceed 30 days.

(4) This section does not substitute any notice or approvals that may be required from another body that regulates the bed capacity, health care facility, or CON-approved service.

(5) A health care facility may not request authorization by the Commission to temporarily delicense bed capacity or the entire health care facility or to temporarily suspend a CON-approved service more than one time in a 1-year period.

(6) No fewer than 30 days before the end of the 1-year or other applicable period, a health care facility that has temporarily delicensed bed capacity or its entire facility or has temporarily suspended a CON-approved service shall notify the Commission that, before the end of the 1-year or other applicable period, it will:

(a) Apply to relicense the bed capacity or the entire facility temporarily delicensed or reimplement the CON-approved service temporarily suspended pursuant to this subsection;

(b) Submit and receive the Executive Director's approval of a specific plan for the relicensure of the bed capacity or facility or for the reimplementation of the temporarily suspended CON-approved service, that:

(i) Imposes stated time frames by which steps toward the relicensure of the bed capacity or facility or reimplementation of the service will be accomplished, or the bed capacity, facility, or service will be deemed abandoned; and

(ii) May be revised upon a proposal by the owner or operator, with the approval of the Executive Director;

(c) File a letter of intent, followed within 60 days by a Certificate of Need application, or request the applicable level of Commission action pursuant to Regulations .03 and .04 of this

chapter, for the relocation of the bed capacity or facility, or for a capital expenditure deemed necessary to relicense the temporarily delicensed beds or facility or necessary to reimplement the temporarily suspended CON-approved service;

(d) Execute a binding contract to transfer ownership of the health care facility, if the requirements of §A of this regulation are met;

(e) Execute a binding contract to transfer ownership of the previously licensed bed capacity, contingent on the filing within 90 days for those filings not subject to a published review cycle or upon the Commission's next published review schedule of a letter of intent to apply for CON approval, or other applicable level of Commission action pursuant to Regulations .03 and .04 of this chapter if required, to relocate the bed capacity; or

(f) Relinquish the bed capacity or the authorization to provide the CON-approved service, or seek the appropriate Commission approval to delicense and permanently close the health care facility.

(7) The Executive Director may extend the period of a temporary delicensure or temporary service suspension under this subsection beyond 1 year for good cause.

(8) An application for a CON to reimplement at another location any previously operating bed capacity that has not operated for 2 or more years shall demonstrate that the bed capacity is needed in the jurisdiction.

(9) Abandonment of bed capacity, health care facility, or service.

(a) If, at the end of the 1-year period or other time period permitted under this section, the requirements of §C(5) or (7) of this regulation have not been met, no request for an extension of time has been granted pursuant to §C(6) of this regulation, and the previously delicensed bed capacity or facility has not been relicensed or the previously suspended service has not been reimplemented, the bed capacity, health care facility, or service is deemed abandoned by its owner or operator.

(b) The Commission shall issue a written notice to the owner of the affected facility, and to its licensed operator if the facility is not operated by its owner, of the opportunity to respond within 30 days before the abandonment is considered final, in order to demonstrate that the previously delicensed bed capacity or facility has been relicensed or the previously suspended service has been reimplemented.

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E. A CON is not required to relocate an existing health care facility owned or controlled by a merged asset system, if:

(1) The proposed relocation is not across jurisdictional boundaries and is to a site in:

(a) The primary service area of the hospital to be relocated; or

(b) The service area of the non-hospital health care facility to be relocated;

(2) At least 45 days before the proposed relocation, notice is filed with the Commission, which will publish notice of the proposed relocation in the Maryland Register and a newspaper of general circulation in the affected area; and

(3) The relocation of the existing health care facility does not:

(a) Change the type or scope of health care services offered; and

(b) In the case of a hospital, require a capital expenditure that exceeds the hospital capital threshold, except as provided in §J of this regulation.

F. Change in Bed Capacity.

(1) A CON is not required to increase or decrease bed capacity if:

(a) For a health care facility that is not an acute general hospital, the change does not exceed ten beds or 10 percent of the facility's total bed capacity, whichever is less, and the facility's licensed bed capacity has not changed in the preceding 2 years;

(b) For a special rehabilitation hospital or a residential treatment center, the change does not exceed ten beds or 40 percent of its current bed capacity, whichever is less, and the facility's licensed bed capacity has not changed in the preceding 2 years;

(c) For an acute general hospital located in a jurisdiction with three or more acute general hospitals, the change:

(i) Is between hospitals in a merged asset system located within the same health planning region;

(ii) Does not involve comprehensive care or extended care beds;

(iii) Does not occur earlier than 45 days after a notice of intent to reallocate bed capacity is filed with the Commission; and

(iv) Does not create a new health care service through the relocation of beds from one jurisdiction to another jurisdiction pursuant to this subsection;

(d) The change in bed capacity is the result of the annual recalculation of licensed bed capacity in acute general hospitals provided for under Health-General Article, §19-307.2, Annotated Code of Maryland;

(e) For an existing medical service provided by an acute general hospital:

(i) The total bed capacity of the hospital does not increase;

(ii) The change is maintained for at least a 1-year period, unless modified pursuant to CON or exemption from CON, or as a result of the annual recalculation of hospital licensed bed capacity required at Health-General Article, §19-307.2, Annotated Code of Maryland; and

(iii) The hospital notifies the Commission at least 45 days before the proposed change in bed capacity of its medical services; or

(f) At least 45 days before increasing or decreasing bed capacity, written notice of the intent to change bed capacity is filed with the Commission, and the increase or decrease in bed capacity will occur in:

(i) An existing general hospice that has a current license issued by the Secretary and involves an increase in bed capacity for the provision of inpatient hospice care under the facility's current license; or

(ii) An existing intermediate care facility that offers residential or intensive substance-related disorder treatment services for withdrawal management and treatment under the facility's current license issued by the Secretary.

(2) Except as otherwise provided in this regulation, a CON is not required to decrease bed capacity at a health care facility if at least 45 days before decreasing bed capacity, written notice of the intent to change bed capacity is filed with the Commission.

G. A CON is not required for a non-hospital health care facility project by a health maintenance organization if:

(1) At least 90 percent of the patients who will receive health care services from the facility are enrolled in the health maintenance organization;

(2) The health maintenance organization requests a determination of coverage from Commission staff that describes its proposed project, including its street address, and the health care service to be provided; and

(3) Commission staff issues a determination that CON or other Commission review is not required.

H. A home health agency is not required to obtain a CON to open a branch office, as defined by the Centers for Medicare and Medicaid Services at 42 CFR §484.2, although notice to the Commission is required.

I. Religious Orders.

(1) A CON is not required before a religious order seeks licensure to operate a comprehensive care facility for the exclusive use of members of that religious order, provided that the religious order seeks and receives a determination of coverage from Commission staff that a CON is not required.

(2) The request for a determination of coverage shall provide the following:

(a) The name and address of the facility;

(b) The number of beds in the facility;

(c) The name of the religious order that will own and operate the facility;

(d) An affirmation that the facility will be owned and operated by the religious order for the exclusive use of its members; and

(e) Agreement to participate in the Maryland Long-Term Care Survey, authorized by COMAR 10.24.03.

(3) Commission staff shall issue a determination that either CON review is not required, with or without conditions, or that CON review is required for stated reasons.

J. Hospital Capital Expenditures in Excess of the Hospital Capital Threshold.

(1) A CON is not required by a hospital before it obligates an amount exceeding the hospital capital threshold for capital expenditures for physical plant construction or renovation, or before it receives a donated physical plant whose appraised value exceeds the hospital capital threshold, under the following circumstances:

(a) The capital expenditure may be related to patient care.

(b) The capital expenditure does not require, over the entire period or schedule of debt service associated with the project or plant, a total cumulative increase in patient charges or hospital rates of more than $1,500,000 for the capital costs associated with the project.

(c) At least 45 days before an obligation is made or the physical plant is donated, the hospital provides notice to the Commission and to the Health Services Cost Review Commission, in the form of a written request for determination of coverage, as provided in Regulation .14A of this chapter, which shall contain the following information:

(i) A description of the proposed capital project, including whether it involves new construction, renovation of or additions to the existing physical plant, or the donation of a physical plant, with any necessary adaptations;

(ii) The total capital costs associated with the project;

(iii) The sources and uses of funds to be applied to the project, including hospital equity contributions, if applicable, as documented by audited financial statements of the hospital and relevant subsidiary corporations, if any, from which funds are to be taken;

(iv) A description of the financing arrangement, if applicable, for the proposed project, including the debt service schedule; and

(v) A statement by one or more persons authorized to represent the hospital that the hospital does not require a total cumulative increase in patient charges or hospital rates of more than $1,500,000 for the capital costs associated with the project.

(2) After consultation with the Health Services Cost Review Commission, the Commission shall issue a determination whether CON review is required within 45 days after it receives the information specified in this section. If Commission staff does not issue a determination within 60 days of receipt of all relevant financial information by the Commission and by the Health Services Cost Review Commission, the Commission is considered to have issued a determination that approval of the capital expenditure is not required by the Commission or by the Health Services Cost Review Commission.

(3) Commission staff shall issue a determination that either CON review is not required, with or without conditions, or that CON review is required for stated reasons.

K. Continuation of Specific Exception from Certificate of Need for Continuing Care Retirement Communities.

(1) A comprehensive care facility on the campus of a continuing care retirement community is excepted from CON review, provided that the requirements of Health-General Article, §19-114(d)(2)(ii)(1), Annotated Code of Maryland, and this chapter are met, and that the number of comprehensive care beds located on the campus of the continuing care retirement community does not exceed:

(a) 20 percent of the number of independent living units at a continuing care retirement community that has 300 or more independent living units; or

(b) 24 percent of the number of independent living units at a continuing care retirement community that has fewer than 300 independent living units.

(2) Limited Direct Admission. Notwithstanding the provisions of Health-General Article, §19-114(d)(2)(ii), Annotated Code of Maryland, a continuing care retirement community does not lose its exception from CON when the continuing care community admits an individual directly to a comprehensive care facility within the continuing care community under either of the following circumstances:

(a) Two individuals having a long-term significant relationship are admitted together to a continuing care retirement community and:

(i) The admission occurs after October 1, 1999;

(ii) The admission includes spouses, two relatives, or two individuals having a long-term significant relationship, as defined in Regulation .01B of this chapter and supported by documentary proof in existence for at least 1 year before application to the continuing care retirement community, admitted at the same time, under a joint contract, who are jointly responsible for expenses incurred under the joint contract; and

(iii) One of the individuals admitted under the joint contract will reside in an independent living unit or an assisted living unit; or

(b) An individual is admitted directly into a comprehensive care bed at a continuing care retirement community and:

(i) The individual must have executed a continuing care agreement and must have paid entrance fees that are at least equal to the lowest entrance fee charged by the continuing care retirement community for its independent or assisted living units;

(ii) The individual must pay the entrance fee by the same method, terms of payment, and time frame as a person who immediately assumes residence in an independent or assisted living unit at that continuing care retirement community; and

(iii) The individual admitted to the comprehensive care bed must have the potential for eventual transfer to an independent living unit or assisted living unit at that continuing care retirement community, as determined by the subscriber's personal physician, as defined in Regulation .01B of this chapter.

(3) Under §K(2)(b)(iii) of this regulation, an individual is deemed not to have potential for eventual transfer to an independent living unit or assisted living unit if the individual can qualify

for hospice services under federal Medicare regulations or if the individual has an irreversible condition that would make it unlikely that the individual could transfer to an independent living unit or assisted living unit at the continuing care retirement community. Irreversible conditions include quadriplegia, ventilator dependence, and any end-stage condition.

(4) The total number of comprehensive care beds occupied by individuals who are directly admitted to comprehensive care beds pursuant to §K(2)(b) of this regulation may not exceed 20 percent of the total number of licensed and available comprehensive care beds at the continuing care retirement community.

(5) The admission of the individual directly into the comprehensive care bed pursuant to §K(2)(b) of this regulation may not cause the occupancy of the comprehensive care facility at the continuing care retirement community to exceed 95 percent of its current licensed capacity.

(6) The comprehensive care facility at the continuing care retirement community shall maintain an attestation by the individual's personal physician that the individual has the potential for eventual transfer to an independent living unit or an assisted living unit.

(7) The nursing home administrator of the comprehensive care facility at each continuing care retirement community who admits an individual directly to a comprehensive care bed pursuant to §K(2)(b) of this regulation shall maintain information, in a format specified by the Commission, about each admission in the format required by the Commission and encrypted by the continuing care retirement community so that the individual's identity will not be disclosed. The forms shall be maintained by the nursing home administrator, to be provided to Commission staff upon its request, and shall include:

(a) The number and utilization of licensed comprehensive care beds excluded from Certificate of Need requirements at the continuing care retirement community;

(b) The admission source of each individual admitted pursuant to §K(2)(b) of this regulation to a comprehensive care bed excluded from Certificate of Need requirements at the continuing care retirement community;

(c) For an individual admitted pursuant to §K(2)(b) of this regulation, the amount of and terms of payment for the entrance fee;

(d) The dates of admission and discharge of each individual admitted pursuant to §K(2)(b) of this regulation;

(e) The site to which an individual directly admitted pursuant to §K(2)(b) of this regulation is discharged; and

(f) Any other information as required by Commission staff.

.04 Exemption from Certificate of Need Review.

A. The Commission may exempt from the requirement of CON review and approval the following actions:

(1) Merger or consolidation of two or more hospitals or other health care facilities, if the facilities or an organization that operates the facilities give the Commission 45 days written notice of their intent to merge or consolidate;

(2) Relocation of an existing health care facility owned or controlled by a merged asset system, if:

(a) The relocation is to a site outside:

(i) T~~t~~he primary service area of the hospital~~ealth care facility~~ to be relocated but within the primary service area of the merged asset system; or

(ii) The service area of the non-hospital health care facility to be relocated but within the primary service area of the merged asset system; and

(b) The relocation of the existing health care facility does not:

(i) Change the type or scope of health care services offered; and

(ii) In the case of a hospital, ~~R~~require a capital expenditure for its construction that exceeds the hospital capital ~~review~~ threshold, adjusted for inflation, except as provided by Regulation .03J of this chapter;

(3) A change in the bed capacity of an existing health care facility pursuant to the consolidation or merger of two or more health care facilities, or conversion of a health care facility or part of a health care facility to a non-health-related use, except as provided in Regulation .03F of this chapter;

(4) A change in the type or scope of the health care services offered by a health care facility, if, at least 45 days before increasing or decreasing the volume of one or more health care services, the Commission finds that the proposed change is pursuant to the:

(a) Consolidation or merger of two or more health care facilities;

(b) Conversion of all or part of a health care facility to a non-health-related use; or

(c) Conversion of a hospital to a limited service hospital;

(5) A capital expenditure that exceeds the review threshold for capital expenditure made as part of a consolidation or merger of two or more health care facilities, or conversion of a health care facility or part of a health care facility to a non-health-related use; or

(6) The establishment of a freestanding medical facility through the conversion of an acute general hospital, as provided in §F of this regulation and in COMAR 10.24.19.04C.

B. Unless otherwise provided in this chapter for a specific type of health care facility, complete notice of intent to seek exemption from CON review shall be filed with the Commission at least 45 days before the intended action, and shall include:

(1) The name and location of each affected health care facility;

(2) A general description of the proposed project including, in the case of mergers and consolidations, any proposed:

(a) Conversion, expansion, relocation, or reduction of one or more health care services;

(b) Renovation of existing facilities;

(c) New construction;

(d) Relocation or reconfiguration of existing medical services; or

(e) Change in bed capacity at each affected facility;

(3) The scheduled date of the project's completion;

(4) Identification of each outstanding public obligation;

(5) Information demonstrating that the project:

(a) Is not inconsistent with the State Health Plan;

(b) Will result in the delivery of more efficient and effective delivery of health care services; and

(c) Is in the public interest; and

(6) Any other information, analyses, or other requirements established in State Health Plan regulation for requests seeking exemption from CON review.

C. Notice by the Commission to the Public, Elected Officials, and Other State Agencies.

(1) Within 5 days after it receives a complete Notice of Intent from a health care facility seeking exemption from CON review, the Commission shall publish notice of its receipt:

(a) In at least one newspaper of general circulation in the affected area;

(b) In the next available issue of the Maryland Register; and

(c) On the Commission’s website.

(2) The Commission shall mail the same notice to elected public officials in whose district or jurisdiction the exemption from CON review is proposed.

(3) The Commission shall solicit comments from the affected public, in evaluating whether the action or project proposed for exemption from CON review is in the public interest.

D. Public Informational Hearing.

(1) An acute general hospital shall hold a public informational hearing in the jurisdiction where it is located within 30 days after it has filed with the Commission notice of its intent to:

(a) Close;

(b) Partially close, if the hospital is located in a jurisdiction with fewer than three acute general hospitals; or

(c) Convert to a limited service hospital or freestanding medical facility.

(2) Before holding the public informational hearing, the hospital shall consult with the Commission, to ensure that:

(a) Within 5 days of notifying the Commission of its intent to close, partially close, or convert, the hospital has provided public notice of the proposed closure or conversion and of the time and location of the required public informational hearing and how the public can electronically obtain additional information, including publication in at least one newspaper of general circulation in the affected area; and

(b) The public hearing will address the information required by §D(3) of this regulation.

(3) Requirements for a Public Informational Hearing.

(a) The acute general hospital proposing to close, partially close, or convert to a limited service hospital or freestanding medical facility shall hold a public informational hearing at the hospital or if that is not feasible at a public meeting area near the hospital.

(b) The hospital shall post a notice of the public informational hearing in public areas of its facility and on the landing page of its website.

(c) The hospital shall identify to the public the names of the senior management and Board of Directors attending the ~~meeting~~hearing.

(d) The hospital shall present at least the following information at the public informational hearing:

(i) The reasons for the closure, partial closure, or conversion;

(ii) The plan for transitioning acute care services previously provided by the hospital to residents of the hospital service area;

(iii) The plan for addressing the health care needs of the residents of the hospital service area;

(iv) The plan for retraining and placing displaced employees;

(v) The plan for the hospital's physical plant and site; and

(vi) The proposed timeline for the closure, partial closure, or conversion to a freestanding medical facility.

(e) The public informational hearing shall be recorded.

(f) Within 10 business days after the public informational hearing, the hospital shall make available on its website a recording of the public informational hearing~~meeting~~ and provide a written summary of the hearing, which shall also be provided to:

(i) The Governor;

(ii) The Secretary;

(iii) The governing body of the jurisdiction in which the hospital is located;

(iv) The local health department and the local board of health or similar body for the jurisdiction in which the hospital is located;

(v) The Commission; and

(vi) Subject to State Government Article, §2-1257, Annotated Code of Maryland, the Senate Finance Committee, the House Health and Government Operations Committee, and the members of the General Assembly who represent the district in which the hospital is located.

E. Commission Action.

(1) Unless otherwise provided in this chapter for a specific type of health care facility, the Commission shall issue an exemption from CON review to the health care facility or the merged asset system seeking this determination within 45 days after it receives the notice of intent required by §B of this regulation, if:

(a) The facility or system has provided the information required by the notice of intent, and has held a public informational hearing if required by §D of this regulation; and

(b) The Commission, in its sole discretion, finds that the action proposed:

(i) Is not inconsistent with the State Health Plan or an institution-specific plan developed by the Commission under Health-General Article, §19-119, Annotated Code of Maryland;

(ii) Will result in more efficient and effective delivery of health care services; and

(iii) Is in the public interest.

(2) For any project that the Commission may exempt from CON review under §A of this regulation, for which a final Commission decision has not been issued within 45 days after it receives a complete notice of intent as required by §B of this regulation, Commission staff shall provide a status report at the next Commission meeting and any subsequent Commission meeting stating the reasons for the delay and the expected time frame for issuing its final decision.

(3) CON review is not required and the exemption request shall be deemed approved for any project which the Commission may exempt from CON review under §A of this regulation if final action by the Commission does not occur within 90 days after the facility or system has provided complete notice of intent as required by §B of this regulation and has held a public hearing if required by §D of this regulation.

(4) Upon request, Commission staff shall provide written confirmation that an exemption request has been deemed approved in accordance with §E(3) of this regulation.

F. Freestanding Medical Facility.

(1) In accordance with COMAR 10.24.19.04C and this regulation, the Commission may exempt from CON review the establishment of a freestanding medical facility as a result of a conversion from a licensed acute general hospital.

(2) At least 60 days before the conversion, written notice of intent to convert the licensed general hospital to a freestanding medical facility shall be filed with the Commission in accordance with COMAR 10.24.19.04C.

(3) Provided that all the requirements of this regulation and COMAR 10.24.19.04C are met, the Commission shall grant the exemption if it finds, in its sole discretion, that the conversion:

(a) Is consistent with the State Health Plan;

(b) Will result in the delivery of more efficient and effective health care services;

(c) Will maintain adequate and appropriate delivery of emergency care within the statewide emergency medical services system as determined by the State Emergency Medical Services Board; and

(d) Is in the public interest.

(4) The Commission may approve, approve with conditions, or deny the requested exemption.

(5) Failure to maintain compliance with conditions on an exemption or with the time frame for completion of the conversion may result in withdrawal of the exemption issued by the Commission in accordance with Regulation .12 of this chapter. An exemption holder may request approval of a reasonable modification to the conversion timeline in accordance with Regulation .12A(4) of this chapter.

.05 Ambulatory Surgery Centers: Determination of Coverage and Data Reporting.

A. Determination of Coverage.

(1) A CON is not required for an ambulatory surgery center.

(2) A person shall obtain a determination of coverage from the Commission before:

(a) Establishing a new ambulatory surgery center;

(b) Adding a new operating room or any other rooms in which procedures are performed to an existing ambulatory surgery center; or

(c) Making any change in the information provided for initial determination of coverage.

(3) Change in Location. A determination of coverage for an ambulatory surgery center is issued only for the exact address specified in the determination. A change in address or in the layout of the center before it is built, developed, or established requires a new determination of coverage.

(4) Change in Ownership. A determination of coverage regarding an ambulatory surgery center is issued only for the person specified in the determination. If the principal owner or a majority of other owners of an existing ambulatory surgery center is expected to change, a request for a new determination of coverage shall be filed and include:

(a) A complete list of the existing owners and the post-transaction owners; and

(b) An attestation by the ambulatory surgery center that, subsequent to the issuance of the original determination of coverage, no changes have been made and that, as a result of the planned change in ownership, no changes will be made:

(i) To the physical plant or layout of the ambulatory surgery center; or

(ii) In the surgical specialties provided.

(5) Expiration of Determination of Coverage. A determination of coverage for a new ambulatory surgery center or for new capacity at an existing ASC-P or ASC-1 may be issued and is effective for 2 years from the date of the determination. If that capacity is not built or established within 2 years, the determination of coverage is void.

(6) Notice. Before seeking to establish a new operating room or any other rooms in which procedures are performed, or to make any change in the information provided for initial determination of coverage, a person shall provide notice to the Commission at least 45 days in advance that includes all information required by COMAR 10.24.11.04A.

(7) For purposes of this regulation, all ambulatory surgery centers that are located in the same building and that share any common ownership or control shall be considered one entity, and their operating rooms shall be considered together for purposes of determining coverage under Regulation .02 of this chapter.

(8) Except as provided in this regulation or permitted in the Certificate of Need or exemption criteria in the State Health Plan under COMAR 10.24.11, an ambulatory surgical facility or other entity primarily providing ambulatory surgical services may not relocate beyond an adjacent site or expand its number of operating rooms without obtaining a Certificate of Need.

(9) A CON is not required for ambulatory surgical services provided as part of an office of one or more individuals licensed to practice dentistry under Health-Occupations Article, Title 4, Annotated Code of Maryland, for the purpose of practicing dentistry, if the ambulatory surgical facility is not used in a medical practice other than dentistry.

B. Data Reporting and Annual Survey of Ambulatory Surgical Centers, Facilities, and Providers.

(1) To provide information for the Commission's planning purposes and to determine changes in circumstances and operation that may affect coverage by CON requirements, each existing ambulatory surgery center, facility, office, and provider that primarily provides ambulatory surgical services shall annually provide to the Commission the information required by COMAR 10.24.04.

(2) A person providing ambulatory surgical services who is required to obtain a license under Health-General Article, §19-3B-02(a), Annotated Code of Maryland, shall annually provide the required information on a form provided by the Commission.

.06 Access to Information and Facilities.

To the extent permitted by law, an applicant shall provide access to general information, records, plans and specifications, meetings, sites, and facilities to Commission staff upon proper notice and as is reasonable and necessary in the performance of the Commission's responsibilities. The Commission may require other health care providers to provide similar information.

.07 Preapplication Procedures.

A. Letter of Intent.

(1) A prospective applicant for a Certificate of Need shall submit to the Center for Health Care Facilities Planning and Development a brief letter of intent, with a copy to each local health department in the health planning region. The Center for Health Care Facilities Planning and Development shall formally log all letters of intent upon receipt.

(2) A prospective applicant identified in a letter of intent may be the person or persons who will be the licensee. If the legal entity that will be the licensee has not yet been formed or finalized at the time of filing a letter of intent:

(a) A prospective applicant shall identify the intended ownership and control of the licensee with the same level of specificity as required in §A(3) of this regulation; and

(b) The legal entity that will be the licensee shall be formed at the time of filing an application for a CON.

(3) The letter of intent shall include the following information:

(a) The identity of each person on whose behalf the letter of intent is filed, including:

(i) The name and address of each such person; and

(ii) In the case of a letter of intent filed on behalf of a person that is not a natural person, the date the entity was formed, the business address of the entity, and the identity and percentage of ownership of all persons having an ownership interest of 5 percent or more in the entity;

(b) A description of the proposed project;

(c) The quantity and types of beds or health services involved; and

(d) The specific location and each jurisdiction in which services will be provided, according to the relevant planning region in the State Health Plan for that facility or service.

(4) A letter of intent shall be submitted in accordance with the published review schedule established by the Commission in accordance with Regulation .08D of this chapter, but if no applicable review schedule has been published, a letter of intent may be submitted at any time.

(5) Notice of the receipt of a letter of intent for a project not subject to a published review schedule shall be placed in the Maryland Register, and a 30-day period initiated for the submission of any other letters of intent for comparable projects to be included in a comparative review.

(6) Upon docketing of an application, the letter of intent for that project is no longer valid for purposes of comparative review.

(7) If a letter of intent is submitted for a proposed health care project which might be comparable to a project application which has been submitted but not yet docketed, the projects shall be given a comparative review.

(8) Notwithstanding any other regulation in this chapter, no letter of intent or application shall initiate a comparative review with an earlier filed letter of intent or application if the earlier filed letter of intent predates the later filed letter of intent by a period of more than 60 days, unless the Executive Director finds that the applicant in the earlier filed matter has unreasonably delayed in the advancement of its application through staff's completeness review, and that good cause exists to review the projects in comparative review.

(9) If a person submits a letter of intent for a proposed health care project that might be comparable to an application which has already been docketed, a comparative review may not be conducted.

(10) If an application for a CON is not filed in accordance with Regulation .08A(1) of this chapter, the letter of intent is void.

(11) Letters of intent are subject to public inspection during normal business hours.

B. Preapplication Conference. After the filing of a letter of intent, an applicant may request that the Commission staff arrange a preapplication conference to discuss:

(1) Commission procedures for reviewing the application or applications;

(2) Information and data to be included in the application or applications;

(3) The State Health Plan requirements that may affect the project; and

(4) Other matters relevant to the filing and processing of the application or applications.

C. The discussions in §B of this regulation are informal, and statements at the meetings are not admissible as evidence at a Commission proceeding.

.08 Procedure for Review of CON Applications.

A. Review Schedule.

(1) An application shall be submitted in accordance with the published review schedule established by the Commission in accordance with §D(1) of this regulation, but if no applicable review schedule has been published, an application may be submitted at any time 60 days after the filing of the letter of intent but no more than 180 days after the filing of the letter of intent, unless a shorter period has been approved by the Executive Director.

(2) In a case when need for additional service capacity is projected, the Commission may not docket an application until it has made a final decision on each previously docketed application for a comparable project, unless the most recently published need projections or State Health Plan would support the approval of both projects.

B. Submission of Application.

(1) An application for a CON shall be submitted to the Commission's Center for Health Care Facilities Planning and Development in the form and manner prescribed by the Commission.

(2) The application, and all information supplementing the application, shall be signed by at least one principal of the applicant, who shall sign a statement as follows: "I solemnly affirm under penalties of perjury that the contents of the application (or the supplementary information) are true to the best of my knowledge, information, and belief."

C. Completeness Review and Docketing.

(1) Prior to docketing an application for review, Commission staff shall review the application for completeness:

(a) Within 20 business days for projects involving the establishment of a health care facility, the relocation of a health care facility or the introduction by a hospital of cardiac surgery or organ transplantation; and

(b) Within 15 business days for all other projects.

(2) Commission staff may schedule a conference with the applicant within the completeness review period prescribed in §C(1) of this regulation.

(3) Commission staff shall determine whether the application contains all the information requested in the application. If staff determines that the application is not complete, the staff shall make one written request for additional information that specifies the information requested and the 15-business-day deadline for the applicant to supply the requested information. For good cause, staff may make one additional request for information, to which the applicant shall have 10 business days to respond. Additional information may be requested by staff beyond that required to make the application complete, which shall also be subject to a time limit for the applicant to supply the requested information.

(4) If Commission staff determines, based on staff's review of the application and any additional information provided in response to a staff request for additional information, that the application is complete and conforms with the applicable docketing rules in the State Health Plan,

the staff shall docket the application for review and publish notice of the docketing on the next available publication date of the Maryland Register.

(5) If an applicant fails to supply the required information within the specified time limit, staff may dismiss the application. Staff may, at its discretion, extend the response time for an applicant in a noncomparative review, or, with the consent of all applicants, for an applicant in a comparative review, up to an additional 10 business days, or more upon a demonstration of good cause for the additional extension.

(6) Commission staff or a reviewer may:

(a) Request information from the applicant supplementing an otherwise complete application at any time during the review of an application; and

(b) Set reasonable time limits for the applicant to supply the requested information.

D. Notice to the Public.

(1) At least once each year, Commission staff shall publish in the Maryland Register a schedule for conducting reviews of applications for designated services by health planning region, as follows:

(a) The schedule shall include the status of applicable need forecasts found in the State Health Plan or published elsewhere as required by the State Health Plan for conducting the reviews of the designated services by health planning region;

(b) The schedule shall establish application submission dates not sooner than 3 months following the publication of the proposed schedule; and

(c) The schedule shall identify scheduled reviews by health planning region and shall state the dates for the receipt of letters of intent and the submission of applications.

(2) Within 10 business days of receiving a complete application, Commission staff shall request that the Maryland Register publish notice to the public of the docketing of an application. The Commission shall also publish notice in a newspaper of general circulation in the area of the proposed project. Notices shall comply with State Government Article, §10-207, Annotated Code of Maryland, and shall include:

(a) A citation to the Commission's enabling act and this chapter, the name of the applicant, the matter or docket number, and a general description of the project containing the information required in letters of intent;

(b) An explanation that a person who meets the definition of "interested party" in Regulation .01B of this chapter may become an interested party to the review of this application by submitting written comments on the application within 30 days of its docketing; and

(c) A statement that a person may request in writing that the Commission advise them of further notices of the proceedings on the application, and that any further notice of proceedings will only be sent to persons who have submitted a written request.

(3) If an evidentiary hearing is held in accordance with Regulation .11 of this chapter, the Commission shall provide notice to each person who has requested to be apprised of further proceedings on the application.

E. Modifications to Letters of Intent and Applications.

(1) An applicant shall give written notice to the Center for Health Care Facilities Planning and Development of any modifications to the applicant's letter of intent before submitting an application.

(2) An application may be modified until the 45th day after docketing. After the 45th day of docketing, an application may only be modified as a result of a project status conference held pursuant to Regulation .09A(2) of this chapter or upon a showing of good cause.

(3) If an application is modified:

(a) The Commission shall provide:

(i) Notice of the changes by a dated posting on the Commission's website and in a newspaper of general circulation in the affected jurisdiction; and

(ii) A 10-business-day period following the website posting for comments on the changes; and

(b) Each applicant in the review will be deemed to have waived the right to a final decision by the Commission within the statutorily prescribed time.

(4) The following modifications to a proposed project require a new Certificate of Need application:

(a) Changes in the fundamental nature of a proposed facility or the medical services to be provided;

(b) Increases in the total bed capacity of a proposed facility; or

(c) A change in the site of a proposed facility.

F. Comments by a Person Seeking Interested Party Status or by a Participating Entity and Applicant's Response.

(1) Written Comments by a Person Seeking Interested Party Status.

(a) A person seeking interested party status shall file written comments on an application within 30 days of docketing.

(b) The comments shall include information sufficient to establish interested party status, as defined in Regulation .01B of this chapter.

(c) If a person seeking interested party status is opposing an application, the comments shall state with particularity the State Health Plan standards or the review criteria in §G of this regulation that the person seeking interested party status believes have not been met by the applicant and the reasons why the applicant does not meet those standards or criteria.

(d) Factual assertions made in comments by a person seeking interested party status that are not included in the record shall be accompanied by appropriate documentation and sworn affidavit.

(e) In a review with only one applicant, the comments shall be 25 pages or fewer, double-spaced, excluding attachments.

(f) In a comparative review, the comments shall be 35 pages or fewer, double-spaced, excluding attachments.

(2) Written Comments by a Person Seeking Participating Entity Status.

(a) A person seeking participating entity status shall file written comments on an application within 30 days of docketing that:

(i) Include information that the participating entity wishes the Commission to consider; and

(ii) State with particularity the State Health Plan standards or review criteria in §G of this regulation that it believes have not been met by the applicant, and the reasons why the applicant does not meet those standards or criteria.

(b) A person granted participating entity status shall be copied on Commission documents in the review of the application.

(c) A person granted participating entity status is not an interested party and has no right to judicial review of a final Commission decision.

(3) Response to Comments.

(a) An applicant is permitted to make one written filing responding to all written comments on its application within 15 days of receipt of those comments.

(b) The applicant's response may not be more than 25 pages, double-spaced, excluding attachments.

(c) In a comparative review, the applicant's response may not be more than 35 pages, double-spaced, excluding attachments.

(d) Factual assertions in an applicant's response that are not included in the record shall be accompanied by appropriate documentation and sworn affidavit.

G. Criteria for Review of Application.

(1) In a Certificate of Need review, the applicant carries the burden of proving by a preponderance of the evidence that the project meets the applicable criteria for review.

(2) In reviewing an application for a CON, the Commission shall consider the applicant's submissions, the comments, if any, of interested parties, participating entities, the local health department, and information gathered during the Commission's review of the application, to which each applicant and interested party has been afforded the opportunity to respond. In a comparative review the Commission shall award a CON to the applicant, or applicants, that best meet the review criteria in §G(3) of this regulation.

(3) Criteria for Review of an Application for Certificate of Need.

(a) State Health Plan. An application for a Certificate of Need shall be evaluated according to all relevant State Health Plan standards.

(b) Need. The Commission shall consider the applicable need analysis in the State Health Plan. If no State Health Plan need analysis is applicable, the Commission shall consider whether the applicant has demonstrated a need for the proposed project.

(c) Alternatives to the Project. The Commission shall consider the alternative approaches to meeting the need identified for the project that were considered by the applicant in planning the project and the basis for the applicant's choice of the project among considered alternatives. In a comparative review of applications within the same review cycle, the Commission shall compare the costs and the likely effectiveness of alternative projects in meeting identified needs, improving the availability and accessibility of care, and improving the quality of care.

(d) Project Financial Feasibility and Facility or Program Viability. The Commission shall consider the availability of resources necessary to implement the project and the availability of

revenue sources and demand for the proposed services adequate to ensure ongoing viability and sustainability of the facility to be established or modified or the service to be introduced or expanded.

(e) Compliance with Terms and Conditions of Previous Certificates of Need. An applicant shall demonstrate compliance with all terms and conditions of each previous CON granted to the applicant.

(f) Project Impact. The Commission shall consider the impact of the proposed project on the costs and charges of existing providers of the facilities and services included in the project and on access to those facilities and services in the service area of the project.

(g) Health Equity. The Commission shall consider how a proposed project will address health care disparities in availability, accessibility, and quality of care among different populations within the service area. The Commission shall consider how social determinants of health within the service area of the proposed project create disparities in the delivery of health care.

(h) Character and Competence. The Commission shall assess the character and competence of an applicant based upon experience and past performance, including any records of violation in operating a health care service or facility.

.09 Commission Decision and Action on CON Applications.

A. Proposed Decision.

(1) Preparation of Proposed Decision.

(a) In a comparative or contested review, or in a review in which an evidentiary hearing is held in accordance with Regulation .11 of this chapter, the Executive Director shall appoint a single Commissioner, who may be assisted by the staff of the Commission, to act as reviewer and prepare a proposed decision for consideration by the Commission.

(b) In all other reviews, Commission staff shall review the application and prepare a staff report and recommendation for consideration by the Commission.

(2) Project Status Conference.

(a) The reviewer or staff, as appropriate, may request that a project status conference be held before the issuance of a proposed decision or staff report, to apprise each applicant, interested party, and participating entity of those aspects of a proposed project that appear to be inconsistent with applicable standards and review criteria.

(b) Following the project status conference, the reviewer or staff will send each applicant, interested party, and participating entity a summary of the project status conference that includes dates, as needed, for additional filings.

(c) The applicant shall send to each interested party and participating entity a copy of proposed project changes made pursuant to the project status conference.

(d) Each interested party and participating entity in the review of an application shall have 7 days to file comments on the proposed changes made pursuant to the project status conference.

(3) Opportunity to Present Oral Argument. Each applicant and interested party in a contested or comparative review may request the opportunity to present oral argument to the reviewer before the reviewer prepares a proposed decision on the application for consideration by the full Commission, as follows:

(a) The request shall be made within the time period for an applicant's response to comments under Regulation .08F(1) of this chapter;

(b) The decision to grant oral argument is at the sole discretion of the reviewer;

(c) The reviewer may set reasonable time limits for oral argument; and

(d) The reviewer may, if there is a genuine dispute as to the credibility of a material witness on a matter of fact, require the witness to answer questions on that matter under oath during the oral argument portion of a CON review.

(4) A staff report and recommendation on a proposed project or a reviewer's proposed decision on a project shall state the staff's conclusion or the reviewer's finding as to whether:

(a) Each relevant State Health Plan standard or review criterion set forth in Regulation .08G of this chapter:

(i) Is met by the applicant;

(ii) Is not applicable to the project; or

(iii) Is applicable to the project and is not met by the applicant;

(b) In a comparative review, one or more of the projects is preferred under a State Health Plan standard or criterion either as a result of consideration of a preference standard or because one or more of the projects was determined to be superior based on the reviewer's consideration of the applicable criteria; and

(c) To recommend that one or more of the projects be granted a CON.

B. Exceptions.

(1) Pursuant to State Government Article, §10-216, Annotated Code of Maryland, each applicant and interested party who has submitted comments under Regulation .08F(1) of this chapter may submit written exceptions to a staff report and recommendation or a proposed decision and make oral argument to the Commission.

(2) Schedule.

(a) A proposed decision in a contested or comparative review shall be issued at least 30 days before the Commission meeting at which the proposed decision and order will be considered.

(b) Upon issuance of a staff report or proposed decision, Commission staff shall issue a notice specifying the schedule for the submission of exceptions and any response, the date on which the Commission shall hear oral argument, and rules for conduct of the hearing.

(c) Unless otherwise agreed by each applicant and interested party, the schedule issued by Commission staff in a contested or comparative review shall specify that exceptions shall be filed on a date at least 10 days after the issuance of a proposed decision and any response to the exceptions filed on a date at least 7 days after the filing of exceptions. The Commission staff may shorten these periods by agreement of the parties, or extend any deadlines set for good cause shown.

(3) Exceptions Requirements.

(a) Exceptions shall specifically identify each finding and conclusion to which exception is taken, citing those portions of the record on which each exception is based.

(b) Exceptions shall be limited to 25 pages, double-spaced, excluding attachments.

(c) Responses to exceptions shall be limited to 15 pages, double-spaced, excluding attachments.

(4) Oral arguments before the full Commission concerning the proposed decision are limited to 10 minutes per applicant and 10 minutes per interested party, unless extended by the Chair of the Commission. An applicant may reserve time for rebuttal.

C. Participation By Participating Entity In Certain Reviews After Issuance of a Staff Report or Reviewer's Proposed Decision.

(1) Request by Participating Entity to Address the Commission.

(a) After the issuance of a staff report or a reviewer's proposed decision, a participating entity may request the opportunity to address the Commission before Commission action on the

application by submitting a written request at least 7 days before the scheduled Commission meeting that will consider an application, specifying the points that it wants to make.

(b) The Chair of the Commission, after consultation with the Executive Director, may permit a participating entity, or combination of participating entities, to make an oral presentation to the Commission on matters it addressed in written comments on the application.

(c) At least 5 days before the scheduled Commission meeting that will consider an application, the Executive Director shall advise each applicant, interested party, and participating entity in a review whether the Chair will permit a participating entity or combination of participating entities to make an oral presentation to the Commission, and shall specify the format of the presentation.

(2) An applicant may address the Commission in any review in which a participating entity is granted permission to address the Commission before action on an application.

D. Final Decision.

(1) The Commission's final decision on a project shall contain findings of fact and conclusions of law and:

(a) Approve the application;

(b) Approve the application with conditions; or

(c) Deny the application.

(2) The decision of the Commission shall be by a majority of the quorum present and voting.

E. Action on the Application.

(1) The Commission shall act on an application for a CON not later than 150 days after the application has been docketed. If no evidentiary hearing is held, the Commission shall act on an application within 90 days after the docketing of the application. Staff shall report to the Commission the status of all projects where a staff report is not issued for Commission action within 90 days.

(2) With the exception of CON applications to establish a health care facility, relocate a health care facility, or establish cardiac surgery services or organ transplantation services at an existing acute general hospital, a CON application filed after October 1, 2019 shall be deemed approved if the application is uncontested and final action by the Commission does not occur within 120 days after the application is docketed.

(3) On motion by an applicant or an interested party, a review of a CON application may be stayed for a period not to exceed 6 months if the reviewer, or if a reviewer is not appointed, the Executive Director, determines that there is good cause for a stay.

(4) The Commission shall notify the applicant, interested parties, participating entities, and the local health department of the Commission's final decision.

(5) The Commission may not render a final decision until:

(a) A staff report and recommendation or a reviewer's proposed decision has been provided to each party; and

(b) Each applicant and interested party has been given an opportunity to file exceptions and present oral argument before the Commission.

F. Judicial Review.

(1) The Commission's final decision is subject to judicial review under State Government Article, Title 10, Subtitle 2, Annotated Code of Maryland.

(2) In order to seek judicial review, a party must be an aggrieved party.

(3) For purposes of judicial review, the record of the proceeding shall include:

(a) The application;

(b) Requests to an applicant for additional information from Commission staff, the reviewer, the Commission, and responses to the requests;

(c) Comments received from each interested party and responses from each applicant;

(d) Reports or recommendations from staff;

(e) Motions and responsive filings;

(f) The prehearing conference report, if any;

(g) Prefiled testimony, if any;

(h) A recording or transcript of any hearing;

(i) The reviewer's proposed decision, all exceptions, and responses to exceptions; and

(j) The Commission's final decision.

(4) A decision of the Commission is a final decision for purposes of judicial review.

(5) A request for reconsideration in accordance with Regulation .19 of this chapter will stay the final decision of the Commission for purposes of judicial review until the Commission decides the request for reconsideration.

.10 Miscellaneous Rules and Procedures.

A. Computation of Time.

(1) In computing a period of time prescribed by these regulations, by order of the Commission, or by an applicable statute, the day of the action or default initiating the designated period of time is not included. The last day of the period so computed is to be included unless it is a day on which the office of the Commission is closed, in which event the period extends until the next day on which the office of the Commission is open. Unless otherwise noted, all time periods shall be computed in calendar days.

(2) At the discretion of the reviewer, the Executive Director, or the Executive Director's designee, and upon a showing of good cause by the submitting party, a period of time to submit a document or perform any act permitted or prescribed by these regulations may be extended for a reasonable period of time.

B. Filing of Documents. In all matters before the full Commission, filings may not be made directly to individual commissioners except at the direction of the reviewer or the Executive Director.

C. Motion Practice.

(1) A motion shall be made in writing, except when made at a hearing or prehearing conference in accordance with Regulation .11 of this chapter, and shall state concisely the action the movant desires the Commission to take, and supporting grounds and authority.

(2) A motion shall be filed within 20 days of the determination to which the motion responds.

(3) The following actions shall be taken by motion:

(a) A demand for an action which the movant desires the Commission, the reviewer, or the staff of the Commission to take;

(b) A request for reconsideration, under Regulation .19 of this chapter;

(c) An objection to the introduction of a statement or other evidence by a party during an evidentiary hearing held under Regulation .11 of this chapter;

(d) A challenge to a reviewer or other member of the Commission;

(e) An action that might be initiated properly or undertaken by a party to a review, and that is not otherwise provided for in this chapter; and

(f) Any other question that is justiciable.

(4) A motion need not be verified unless it is based on facts not apparent from the record or documents filed in the proceeding.

(5) An applicant or interested party to the review may file one written answer to a motion, in the same format required of motions, within 10 days of the filing of the motion.

(6) Except as otherwise provided in these regulations, the reviewer or, in a matter in which no reviewer has been appointed, the Executive Director shall rule on a motion made prior to the issuance of a proposed decision or staff recommendation. Except as otherwise provided in these regulations, the Chair shall rule on all other motions.

(7) The person presiding over the motion may hear oral argument on the motion at the request of a party.

D. Summary Decision.

(1) At any time after an application is docketed, staff may file a motion for summary decision to deny the application.

(2) The motion shall identify the grounds for the motion, which is not required to address every applicable State Health Plan standard. The applicant may respond to the motion in writing, within 15 days of receipt of the motion.

(3) The reviewer, or, in a matter in which no reviewer has been appointed, a commissioner appointed as motions officer by the Executive Director, may hear oral argument on the motion at the request of a party and shall issue a proposed ruling which shall be subject to review by the full Commission.

(4) A quorum of the full Commission shall make a final ruling on the motion for summary decision.

E. Ex Parte Contacts. After the docketing of an application and until the Commission renders its final decision under this regulation, the ex parte provisions of the State Government Article, Title 10, Annotated Code of Maryland, apply.

F. Local Health Department Review and Comment. The Commission shall seek information and comment from each local health department in the health planning region for the proposed project, and shall consider any response from each health department in making a final decision on an application.

G. Required Approvals.

(1) Except in emergency circumstances posing a threat to public health, all decisions of the Commission on an application for a Certificate of Need shall be consistent with applicable State Health Plan standards and criteria established by the Commission.

(2) Unless the Commission finds that the facility or service for which a proposed expenditure is to be made is not needed or is not consistent with the State Health Plan, the Commission shall approve an application for a Certificate of Need to the extent that the expenditure will be made to eliminate or prevent an imminent safety hazard, as defined by federal, State, or local fire, building, or life safety codes or regulations, to comply with State licensing standards, or to comply with accreditation standards for reimbursement under Title XVIII of the Social Security Act or under the State Medical Assistance Program approved under Title XIX of the Social Security Act.

H. Notice of Final Action on a Certificate of Need Application. The Commission shall provide a copy of a CON decision to State or local licensing agencies, the Maryland Medical Assistance Program, and the Health Services Cost Review Commission.

I. Participation of Staff. A reviewer may seek the assistance of any member of the Commission staff in preparing a proposed decision.

J. Transferability. A Certificate of Need or other Commission approval is not transferable.

K. Consent Agenda.

(1) The Commission may take action on the following categories of items by use of a consent agenda at a public meeting of the Commission:

(a) Adoption of final regulations previously adopted by the Commission as proposed permanent regulations that:

(i) Do not result in public comments after publication in the Maryland Register; and

(ii) Contain no wording changes.

(b) A change in an approved project that requires Commission approval pursuant to Regulation .17 of this chapter and is recommended for approval by the Executive Director with the exception of:

(i) An increase in the capital cost of a project that exceeds the approved capital cost inflated by the cost index specified in Regulation .17 of this chapter that also includes a change in the financing mechanism of the project; or

(ii) A change in the financing mechanism of the project.

(c) Confirmation of an emergency CON issued by the Executive Director in accordance with Regulation .20 of this chapter.

(d) Other categories of actions that a majority of the fully authorized membership of the Commission votes to include on the consent docket.

(2) Consent agenda items shall be disseminated to the Commissioners prior to the meeting along with copies of any related materials. At the beginning of the meeting, the Chair of the Commission will present the consent agenda to the Commissioners and ask whether anyone wishes to remove an item from the consent agenda to the main agenda or the next scheduled meeting. Items may be removed from the consent agenda on the request of any one Commissioner. Items not removed may be adopted by general consent without debate. Removed items may be taken up either immediately after the consent agenda, placed later on the agenda, or moved to the meeting that follows at the discretion of the Chair.

.11 Evidentiary Hearings.

A. Request for Evidentiary Hearing.

(1) Except as otherwise provided in these regulations, a request for an evidentiary hearing shall be made within 45 days of the docketing of an application or within 30 days after the modification of an application in a review.

(2) At the request of an applicant or interested party, the Commission may hold an evidentiary hearing in the review of a CON application for any health care facility other than an ambulatory surgical facility if, in the judgment of the reviewer, an evidentiary hearing is appropriate due to the magnitude of the impact that the proposed project may have on the health care delivery system and the project, if approved, would result in one of the following:

(a) A substantial negative impact on the costs and charges for the type of the facility, services, or both included in the project;

(b) A substantial negative impact on access to those facilities and services by the population in the proposed project's expected service area;

(c) A significant decrease in the availability and overall quality of health care services in the affected area in a manner not consistent with policies or need projections set forth in the State Health Plan, such as by causing a loss of reasonable access to an essential medical service by a substantial number of patients; or

(d) Any impact that the reviewer concludes may be sufficiently serious to merit an evidentiary hearing.

B. General.

(1) Reviewer as Presiding Officer.

(a) If an evidentiary hearing is held in accordance with this chapter, the reviewer shall:

(i) Conduct a full, fair, and impartial hearing;

(ii) Take action to avoid unnecessary delay in the disposition of the proceedings; and

(iii) Maintain order.

(b) A reviewer has the power to regulate the course of an evidentiary hearing and the conduct of the parties and authorized representatives, including the power to:

(i) Administer oaths and affirmations;

(ii) Rule upon offers of proof and receive relevant and material evidence;

(iii) Consider and rule upon motions in accordance with this chapter;

(iv) Examine witnesses and call witnesses as necessary to ensure a full and complete record;

(v) Limit unduly repetitious testimony and reasonably limit the time for presentations;

(vi) Grant a continuance or postponement;

(vii) Modify or waive, reasonably and for good cause, any time periods established by this chapter;

(viii) Request that parties submit legal memoranda, proposed findings of fact, and proposed conclusions of law;

(ix) Make proposed decisions and take any other appropriate action authorized by law;

(x) Issue orders as are necessary to secure procedural simplicity and administrative fairness and to eliminate unjustifiable expense and delay; and

(xi) Conduct the hearing in a manner suited to ascertain the facts and safeguard the rights of the parties to the hearing.

(c) The reviewer may impose appropriate sanctions for failure to abide by this chapter or any lawful order of the reviewer.

(2) Conduct of Evidentiary Hearings.

(a) An evidentiary hearing need not be conducted according to technical rules of evidence, but shall be conducted in accordance with the State Government Article, Title 10, Subtitle 2, Annotated Code of Maryland, and these regulations.

(b) Reliable hearsay is admissible.

(c) Rules of privileges are effective to the extent they would be effective in a judicial proceeding in Maryland.

(d) Nonexpert opinion testimony may be considered.

(e) Qualification as an expert lies within the discretion of the reviewer. The qualification of an expert need not be based on academic degrees. Reasonably extensive practical experience with the subject may be sufficient for an expert qualification.

(f) Reliable and probative documents previously filed with or compiled by the Commission or its staff or consultants that are relevant to issues being considered by the Commission may be incorporated by reference into the record of a proceeding by the Commission or, by leave of the reviewer, by a party to the proceeding, upon notice to the parties and an opportunity to object.

(g) The reviewer may take administrative notice of all judicially cognizable facts to the same extent as courts of this State, either on the reviewer's own motion or at the request of a party. The reviewer may also take official notice, without meeting formal evidentiary rules, of general technical or scientific facts within the specialized knowledge of a member of the Commission. A party to the hearing is entitled, on timely request, to an opportunity to show that the Commission should not take administrative or official notice of specific facts and matters, or that the fact or matter to be officially noticed is inapplicable to the proceeding or is incorrect or misunderstood by the Commission.

(3) A party to the hearing may be represented by counsel.

(4) The prehearing conference and the hearing shall be recorded. If an applicant or other person desires a transcript, that person shall pay all costs to transcribe the recording.

(5) Documents filed in the proceeding shall be served on the reviewer, the assistant attorneys general of the Commission, and each interested party, and shall include a certificate of service.

C. Prehearing Procedures.

(1) The reviewer shall hold a prehearing conference, and may hold settlement conferences, before an evidentiary hearing.

(2) The reviewer shall notify each applicant and interested party of the prehearing conference in writing. The notification shall:

(a) Include the date, time, and place of the prehearing conference or conferences;

(b) Summarize the rules of procedure governing the evidentiary hearing; and

(c) State the dates, if known, for the submission of prefiled testimony and the date, time, and place of the evidentiary hearing.

(3) The principal purpose of the prehearing conference is to expedite the evidentiary hearing. To this end the reviewer may, among other things:

(a) Instruct the parties to:

(i) Formulate and submit a list of genuine contested issues to be decided at the hearing;

(ii) Identify each potential witness, the subject matter of each witness's testimony, and documents to be introduced; and

(iii) Raise and address issues that can be decided before the hearing;

(b) Encourage stipulations as to facts, law, and other matters;

(c) Schedule dates for the submission of prefiled testimony, further prehearings, the hearing, and submission of briefs and documents; and

(d) Rule on any pending motions.

(4) A written summary of the prehearing conference shall be made a part of the record of the proceeding.

(5) The reviewer may record the prehearing conference or have a stenographer present.

(6) A request for the postponement of a hearing shall be made at a reasonable time before the hearing and may be granted only for good cause shown, at the discretion of the reviewer.

D. List of Genuine Issues.

(1) The reviewer shall establish a list of genuine issues of material fact for the evidentiary hearing.

(2) An evidentiary hearing shall be held only on those genuine factual issues or issues on which the reviewer determines that testimony would be useful in rendering a decision.

E. Written Direct Testimony.

(1) Direct testimony shall be in writing and may not be delivered orally.

(2) A party who wishes to present testimony at the evidentiary hearing shall file written testimony before the hearing in accordance with the schedule set by the reviewer.

(3) The written direct testimony shall set forth the conclusions of the person submitting it and all arguments and facts supporting these conclusions.

(4) Written direct testimony shall be verified either under oath at the hearing or by including the statement specified in Regulation .08B(2) of this chapter.

(5) Upon notice with an opportunity to object, the reviewer shall separate irrelevant material from the remainder of the record and keep that material apart. Parts of the body of the written direct testimony judged irrelevant by the reviewer shall be so marked and may not be considered by the Commission in its deliberations.

(6) Persons submitting written testimony shall make themselves available for oral cross-examination. Submitted application materials are also subject to cross-examination. Letters submitted into the record which are not considered written testimony are not subject to cross-examination.

F. Cross-Examination.

(1) Cross-examination of each witness shall be live and under oath.

(2) The reviewer and each non-proponent applicant and interested party may conduct reasonable cross-examination of a witness who gave direct or rebuttal testimony.

(3) The reviewer may set reasonable time limits on the cross-examination of witnesses.

G. Rebuttal Testimony.

(1) Rebuttal testimony is permitted on any issue specified by the reviewer.

(2) Rebuttal testimony, whether specified by the reviewer to be written or oral, is subject to live cross-examination.

H. Post-Hearing Briefs. The reviewer may request post-hearing briefs.

I. Informal Proceedings. At the request of an applicant, and if each interested party waives the right to present evidence, argument, and conduct cross-examination, the reviewer may establish informal rules for mediation, structured negotiation, or another consensual procedure for reaching a decision.

.12 Holder Responsibilities and Withdrawal of a Certificate of Need or Other Commission Approval.

A. Project Implementation Schedule.

(1) An application for a CON or other Commission approval shall propose a schedule for implementation of the project that specifies the estimated time for, at a minimum, the following project implementation steps:

(a) The time required to enter a binding obligation following Commission approval of the application for the project;

(b) The time required to initiate construction, renovation, or both following execution of a binding obligation;

(c) The time required to complete the approved construction, renovation, or both following initiation of construction, renovation, or both; and

(d) The time required to place the new facility or modified facility in operation following the completion of approved construction, renovation, or both.

(2) The proposed project implementation schedule for a project requiring a multiphased plan for implementation shall detail those multiple phases and specify the estimated time requirements for, at a minimum, the four time periods listed above for each phase.

(3) A holder shall abide by the project implementation schedule submitted with its application for a CON or other Commission Approval.

(4) The project implementation schedule may be reasonably modified by the holder during the period during which the project is being implemented with approval of Commission staff.

B. Progress Report.

(1) Up until an approved project's completion, licensure, if required, and first use, a holder shall submit a semiannual progress report in the form and manner prescribed by Commission staff.

(2) The semiannual progress report shall detail the holder's compliance with the project implementation schedule and any conditions on approval imposed by the Commission.

(3) A holder shall submit the semiannual progress reports in accordance with the following schedule:

(a) The first report shall be due at least 45 days before the 6-month anniversary of the final action awarding the CON or other Commission approval; and

(b) Subsequent progress reports shall be due every 6 months after the due date of the prior report.

C. Obligation.

(1) Except as provided by §C(2) of this regulation, a holder shall obligate at least 51 percent of the approved capital expenditure for a project involving building construction, renovation, or both, as documented by a binding construction contract or equipment purchase order, within the following specified time periods:

(a) An approved new hospital has up to 36 months to document the required obligation;

(b) A project involving an approved new non-hospital health care facility or involving a building addition or replacement of building space of a health care facility has up to 24 months to document the required obligation;

(c) A project limited to renovation of existing building space of a health care facility has up to 18 months to document the required obligation; and

(d) A project that does not involve construction or renovation shall document that the approved project is complete and operational within 18 months of project approval.

(2) In a multiphased plan of construction with more than one construction contract approved for an existing health care facility, a holder has:

(a) Up to 12 months after approval to obligate 51 percent of the capital expenditure for the first phase of construction; and

(b) Up to 12 months after completion of the immediately preceding phase of construction to obligate 51 percent of the capital expenditure for any subsequent approved phase of construction.

D. Effective Date of a CON or other Commission approval. The effective date of a CON or other approval is the date of Commission action approving the application for the project. If a request for reconsideration is timely filed under Regulation .19 of this chapter, the effective date of the approval is the date the Commission rules on the request. The filing of a notice of appeal does not stay enforcement of the Commission decision.

E. Grounds for Withdrawal of Commission Approval. The Commission may withdraw a CON or other Commission approval if it finds that:

(1) The holder made a material misrepresentation upon which the Commission relied in approving the application;

(2) The holder failed to demonstrate sufficient progress in implementing the project;

(3) The holder has failed to obligate or complete an approved project as required by §A of this regulation;

(4) The holder failed to meet a condition on the approval;

(5) The holder failed to timely provide the semiannual progress report required under §B of this regulation; or

(6) The project differs materially from that approved by the Commission.

F. Notice Before Withdrawal of a CON or Other Commission Approval.

(1) If Commission staff determines that a CON or other Commission approval should be withdrawn, Commission staff shall inform the holder and each appropriate local health department, setting forth in writing the reasons for the proposed withdrawal.

(2) This notice shall set forth the right of the holder to submit written argument in support of its position and present oral argument to the Commission, as well as the right to an evidentiary hearing conducted in accordance with Regulation .11 of this chapter, to show cause why the approval should not be withdrawn.

(3) A holder that has failed to demonstrate sufficient progress in project implementation shall show good cause for the lack of progress.

G. Final action by the Commission withdrawing a CON or other approval shall:

(1) Be in writing;

(2) Include findings of fact and conclusions of law; and

(3) Be transmitted to the holder and to each appropriate local health department within 30 days of the date of action by the Commission.

H. CON Application after Withdrawal of a Prior CON. If a CON or other approval is withdrawn due to lack of sufficient progress in implementing the project, the holder may file an application seeking Commission approval to initiate or complete the previously authorized project, which shall be considered a new application by the Commission.

.13 Procedures for Certificate of Conformance and Certificate of Ongoing Performance Applications.

A. Coverage.

(1) A certificate of conformance is required to introduce primary or elective percutaneous coronary intervention services at a hospital.

(2) A certificate of ongoing performance is required and shall be periodically renewed to certify that a hospital providing cardiac surgery services or percutaneous coronary intervention

services is maintaining an acceptable level of quality and performance in its provision of those services.

(3) A hospital with newly established cardiac surgery services or percutaneous coronary intervention services at an acute general hospital may continue to provide services without a certificate of ongoing performance until the Commission acts on the hospital's first application for a certificate of ongoing performance.

B. Submission of Applications.

(1) An application for a certificate of conformance or a certificate of ongoing performance shall be submitted to the Commission in a form and manner prescribed by the Commission.

(2) An application shall be submitted in accordance with a published review schedule established by the Commission under §E of this regulation, except that applications to establish both primary and elective percutaneous coronary intervention services based on insufficient access under COMAR 10.24.17.04A(2)(b) may be filed at any time.

(3) The application, and all information supplementing the application, shall be signed by at least one principal of the applicant, who shall sign a statement as follows: "I solemnly affirm under penalties of perjury that the contents of this application are true to the best of my knowledge, information, and belief."

C. Completeness Review of Certificate of Conformance Applications.

(1) Commission staff shall review a certificate of conformance application for completeness within 15 business days.

(2) If staff determines the application is not complete, staff may request additional information to make the application complete within the 15-business-day period to review the application. The applicant shall provide full and clear responses to the completeness and additional information request within 15 business days unless an extension is requested and granted.

(3) If Commission staff determines after review of the application and information provided in response to staff's request that the application is complete, staff shall notify the applicant of its determination.

(4) If an applicant fails to supply requested information within the specified time limit, staff may dismiss and return the application.

D. Additional Information. Commission staff may:

(1) Request information from an applicant supplementing an application at any time during the review of an application, provided that such additional information is material to the determination of whether the applicant has satisfied the criteria and standards for approval; and

(2) Set reasonable time limits for the applicant to supply the requested information.

E. Notice to the Public.

(1) At least once each year, the Commission staff shall publish in the Maryland Register a schedule for reviews of:

(a) Certificate of conformance applications to establish primary or elective percutaneous coronary intervention services; and

(b) Certificate of ongoing performance applications if at least one hospital is required to file an application in the time period covered by the schedule.

(2) The Commission shall publish, on its website, information on the receipt of applications for certificates of conformance and certificates of ongoing performance.

F. The Commission shall act on an application for a certificate of conformance not later than 120 days after staff notified the applicant that the application is complete, except for applications reviewed in conjunction with a CON application in accordance with COMAR 10.24.17.04C.

G. Criteria for Review of Applications. Applicable criteria and standards for certificate of conformance reviews and certificate of ongoing performance reviews are specified in COMAR 10.24.17, the State Health Plan chapter for cardiac surgery and percutaneous coronary intervention services.

H. Staff Report and Recommendation. Commission staff shall review a certificate of conformance and certificate of ongoing performance applications and prepare a staff report and recommendation that contains the staff's conclusion as to whether the applicant has met each applicable criterion and standard in COMAR 10.24.17.

I. Exceptions.

(1) An applicant may submit exceptions to a staff report and recommendation and present oral argument on its exceptions to the Commission.

(2) Schedule.

(a) Staff's issuance of a staff report and recommendation shall be accompanied by a notice that specifies the schedule for the submission of exceptions and the date of the Commission meeting at which the Commission shall hear oral argument on exceptions.

(b) Unless otherwise agreed by each applicant and interested party, the schedule issued by Commission staff shall specify that:

(i) A party filing exceptions has at least 10 days to file exceptions; and

(ii) A party filing a response to exceptions has at least 7 days to file a response.

(c) The Commission staff may shorten these periods by agreement of the parties, or extend any deadlines set for good cause shown.

(3) Exceptions shall specifically identify each staff conclusion to which exception is taken, citing those portions of the record on which each exception is based.

(4) Exceptions and any response to exceptions shall be limited to 25 pages, double-spaced, excluding attachments.

(5) Commission staff may file a written response to exceptions and present oral argument at the exceptions hearing.

(6) Oral arguments on exceptions to the staff report and recommendation and any response shall be limited to 10 minutes per argument unless extended by the Chair of the Commission.

J. Final Decision on an Application for Certificate of Conformance.

(1) A final decision on an application for a certificate of conformance shall contain findings of fact and conclusions of law and shall:

(a) Approve the application;

(b) Approve the application with conditions; or

(c) Deny the application.

(2) A certificate of conformance issued by the Commission for an approved application shall specify the period of time for which the initial certificate is effective and the expected date by which the hospital is expected to seek a certificate of ongoing performance for its primary or elective percutaneous coronary intervention services or both.

K. Final Decision on an Application for Certificate of Ongoing Performance.

(1) The Commission's final decision on an application for a certificate of ongoing performance shall contain findings of fact and conclusions of law and shall:

(a) Approve the application;

(b) Approve the application with conditions; or

(c) Deny the application or revoke the Commission’s approval for the involved services provided that all the steps in COMAR 10.24.17 including performance of a focused review and an

opportunity for agreement upon and completion of a plan of correction have been provided to the hospital.

(2) A certificate of ongoing performance issued by the Commission shall specify the period of time for which the certificate is effective and the expected date by which the hospital is expected to seek a new certificate of ongoing performance for its primary or elective percutaneous coronary intervention services or both, as applicable, or for its cardiac surgery services.

(3) The duration of a certificate of ongoing performance may be extended beyond the renewal deadline, if due to extenuating circumstances, the Executive Director determines an extension is necessary and appropriate, prior to staff producing a written report and recommendation to the Commission regarding the hospital's application for renewal of its certificate of ongoing performance.

L. The decision of the Commission shall be by a majority of the quorum present and voting.

M. The decision of the Commission is subject to judicial review in accordance with Regulation .09F of this chapter.

.14 Special Procedures.

A. Determination of Coverage. Except as otherwise provided in Regulations .03 or .05 of this chapter, a project that requires a determination of coverage shall be dealt with in the following manner:

(1) A written request for determination of coverage shall be filed with the Center for Health Care Facilities Planning and Development.

(2) The Executive Director of the Commission shall review the request and act on it within 30 business days of receipt of complete information.

(3) The person requesting the determination shall provide all additional information requested by Commission staff.

(4) The Commission shall notify the person, each appropriate local health department, and each agency responsible under the Department's licensure program for the type of project whether it requires a Certificate of Need or other Commission review.

(5) Commission staff's determination of coverage may be appealed by the requesting party to the Commission by use of a motion filed in accordance with Regulation .10C of this chapter.

(6) The Executive Director may issue a determination that:

(a) Certificate of Need or other Commission review is not required; or

(b) Certificate of Need review is required for stated reasons.

B. Declaratory Rulings.

(1) A person uncertain as to how a statute or regulation enforced by the Commission applies to that person or that person's property may file with the Commission a petition for a declaratory ruling in accordance with the procedures in §B of this regulation.

(2) The Commission may decline to issue a declaratory ruling for any of the following reasons:

(a) The petition is not in accordance with this section;

(b) The petition contains insufficient factual or legal information upon which to base a declaratory ruling;

(c) The petition raises issues adequately addressed in a final decision or regulation of the Commission;

(d) The petition fails to pose a significant issue;

(e) The petition is properly heard as part of an evidentiary hearing; or

(f) A declaratory ruling would not be in the public interest.

(3) Within 15 days of receipt of a petition, the Executive Director shall either assign the petition to the full Commission for a decision or appoint a Commissioner to make a proposed ruling on the petition, which ruling shall be considered by the full Commission.

(4) Within 45 days, or by the second regularly scheduled Commission meeting following the filing of the petition, whichever is later, the Commission shall rule or decline to rule on the petition, or may postpone issuing a formal written declaratory ruling for up to 35 days.

(5) To secure a declaratory ruling, an affected person shall submit a petition for a declaratory ruling that contains the following information:

(a) The petitioner's name, address, and telephone number;

(b) A one or two sentence statement of each question on which a ruling is requested;

(c) A one or two sentence summary of the petitioner's position on each question;

(d) Citation to each provision that the Commission needs to interpret in order to answer each question posed;

(e) A brief statement of each relevant fact;

(f) The petitioner's factual, legal, and policy arguments, referring to documents, affidavits, data, and other relevant information, which shall be appended to the petition, unless the documents are readily accessible to the Commission; and

(g) A statement by the petitioner under penalties of perjury that each fact recited as relevant to the question posed is true to the best of the petitioner's knowledge, information, and belief.

(6) The Commission shall promptly publish notice of the receipt of a petition in the Maryland Register and shall note the petition on meeting agendas until the Commission acts upon the petition.

(7) The Commissioner making a proposed ruling or the Commission, in addition to considering the materials submitted by the petitioner and comments from staff, may:

(a) Request and receive oral or written statements from any person;

(b) Consider any document, data, study, or other relevant material; or

(c) Require argument on the question on the record, giving the petitioner the opportunity to present argument and to proffer witnesses and documents for the Commission's consideration.

(8) The proposed and final declaratory ruling shall be in writing, and state:

(a) Each question addressed;

(b) The proposed or final ruling; and

(c) The factual and legal basis for the ruling.

(9) A final declaratory ruling binds the Commission and the petitioner on the facts set forth in the petition, except when this binding effect violates the due process rights of a competing applicant in a comparative review.

(10) The Commission may revoke, alter, or amend a proposed or final declaratory ruling, which may have prospective effect only.

(11) A petitioner may appeal the declaratory ruling as set forth in State Government Article, Title 10, Annotated Code of Maryland.

.15 Commission Approval Required Before Certain Actions.

A. Obligation of Capital Expenditure.

(1) A person may not incur an obligation for a capital expenditure for a project that is subject to review under these regulations until the applicant receives a CON or other required Commission approval.

(2) An obligation for capital expenditure is incurred by or on behalf of a health care facility:

(a) When a contract, enforceable under State law, is entered into by or on behalf of the health care facility for the construction, acquisition, lease, or financing of a capital asset;

(b) When a governing body of the health care facility takes formal action to commit its own funds for a construction project undertaken by the health care facility as its own contractor; or

(c) In the case of donated property, on the date on which the gift is completed under applicable State law.

B. Obligation of Predevelopment Expenditures. An applicant proposing predevelopment expenditures requiring review under this chapter may not enter into a binding contract or other obligation for such activities until the applicant receives a CON or other required Commission approval.

C. Binding Commitments for Financing. A binding arrangement or commitment for financing a project may not be entered into by an applicant until the applicant receives a CON or other required Commission approval for the project.

.16 Voluntary Withdrawal of an Application.

An applicant may voluntarily withdraw its application without prejudice prior to final action by the Commission on the application. Written notice of the withdrawal shall be submitted to the Commission through the Executive Director. A withdrawn application may be resubmitted at a later date as a new application.

.17 Project Changes After Commission Approval.

A. Filing of Request. A holder that desires to change a project that has received CON or other Commission approval shall submit a request for the proposed change and supporting documentation to the Commission, copying each local health department within the health planning region of the project and, in the case of a change in the location or address of a project involving construction of a new health care facility, to all health care facilities of that type located in the health planning region.

B. Commission Approval Required Before Project Changes. Any of the following proposed changes that would place the project at variance with its CON or other approval issued under this chapter, including any condition placed on the approval, shall be reviewed by the Commission:

(1) A significant change in physical plant design;

(2) A capital cost increase that exceeds the approved capital cost inflated by an amount determined by applying the Hospital Capital Market Baskets published by IHS Markit in Health Care Cost Review or other guidance approved by the Commission and posted on the Commission

website from the application submission date to the date of the filing of a request for a project change;

(3) A change in the financing mechanisms of the project; or

(4) A change in the location of the project.

C. Impermissible Changes. The following proposed changes to an approved project require a new CON or other appropriate review and may not be considered by the Commission:

(1) Changes in the fundamental nature of a facility or the services to be provided in the facility from those that were approved by the Commission;

(2) Increases in the facility's total bed capacity or operating room inventory; or

(3) Changes in the medical service provided or approved.

D. Commission Action.

(1) Requested changes subject to review under §B of this regulation shall be reviewed by the Commission.

(2) Within 5 days after the Commission's receipt of a written request to change the address or location of an approved project, Commission staff shall arrange to publish notice of receipt of the change request in the Maryland Register and one newspaper of general circulation in the appropriate health planning region, shall post the notice on its website, and shall provide written notice of receipt of the change request to:

(a) Each member of the General Assembly in whose district the relocation is planned;

(b) Each member of the governing body for the jurisdiction in which the relocation is planned; and

(c) The county executive, mayor, or chief executive officer, if any, in whose county or city the relocation is planned.

(3) The Commission shall provide a written notification within 45 days of the Commission's receipt of a complete change request that:

(a) The proposed change is approved in whole or part and incorporated into a modified CON or other modified approval for the project with conditions as appropriate; or

(b) The proposed change is denied, with explanation.

.18 Review Required Before Licensing or First Use of Project.

A. Request for First Use Review and Approval. Not fewer than 60 days but not more than 120 days before the first use of any portion of a facility or service developed under a CON or other

Commission approval, the holder shall specify the anticipated date for first use and request in writing, through the Center for Health Care Facilities Planning and Development, a final review and first use approval. The request shall include:

(1) Documentation of the final cost of the project; and

(2) A description of any differences in physical plant design, space, or services in the finished project when compared with the description of the project reviewed and approved by the Commission.

B. Action on Request. Within 30 days of receipt of all required information, Commission staff shall issue an approval for first use or a finding that the project does not conform to its CON or other Commission approval. Issuance of first use approval is not a new final decision concerning a CON and may not be appealed.

C. Nonconformance with CON or Other Commission Approval. If the Executive Director finds that a project does not conform to its CON or other approval, the applicant may not proceed to licensure or first use until the Executive Director issues a written finding that the project conforms with its approval. Based on a finding that a project varies significantly from the project that was granted a CON or other approval, the Executive Director may invoke the full review process established in Regulation .04, Regulations .08—.10, and Regulation .13 of this chapter in order to reexamine the project.

D. Duration of First Use Approval. First use approval remains in effect for 90 days. If a project is not put into use within that 90-day period, the holder shall reapply for first use approval.

.19 Reconsideration Procedures.

A. Request for Reconsideration. An aggrieved party may request that the Commission conduct a hearing to reconsider a Commission final decision to grant, to grant with conditions, or to deny a Certificate of Need application, a request for an exemption from CON review, or a certificate of conformance application issued under this chapter. This request shall be in writing and filed with the Center for Health Care Facilities Planning and Development within 15 days of the date upon which the Commission renders its decision and shall show good cause for reconsideration of the decision.

B. Good Cause. For purposes of this regulation, a request for a reconsideration shows good cause if it:

(1) Presents significant, relevant information which was not previously presented to the Commission and which, with reasonable diligence, could not have been presented before the Commission made its decision;

(2) Demonstrates that there have been significant changes in factors or circumstances relied upon by the Commission in reaching its decision; or

(3) Demonstrates that the Commission has materially failed to follow its adopted procedures in reaching its decision.

C. Notice of Reconsideration Request. At least 15 days prior to the date the Commission will consider a request for reconsideration, the Commission shall provide written notice of the date to the person making the request, each applicant, each interested party, and each relevant local health department. Each interested party may file a written response.

D. A request to present oral arguments shall be made at the time of filing an initial request for reconsideration or a response.

E. If the Commission determines that good cause has been demonstrated, the Commission may reverse or modify its previous decision. Within 30 days, the Commission shall issue a new decision containing written findings of fact and conclusions of law stating the basis for its decision, which shall be its final decision for the purpose of judicial review.

.20 Emergency Certificate of Need.

A. The Executive Director may issue an emergency Certificate of Need under the following circumstances that would otherwise require issuance of a CON:

(1) A situation presents hazards to employees or patients of a health care facility, and the project required to address the situation would otherwise require CON review;

(2) The closing of a health care facility by State licensing authorities requires changes or adjustments in other facilities to accommodate displaced patients, and the changes or adjustments would otherwise require that these facilities obtain a CON under these regulations; or

(3) A project that would require CON review is necessary to address a public health emergency and cannot be delayed.

B. Procedure for an Emergency Certificate of Need.

(1) A health care facility may apply for an emergency CON by sending a signed letter in PDF format by email and hard copy to the Executive Director that contains:

(a) A description of the project for which an emergency CON is sought;

(b) An explanation of the need for emergency action;

(c) The location and current use of the space where the proposed project will be implemented;

(d) The time frame by which the project can be implemented;

(e) Approximate cost, if known; and

(f) Status of existing unused physical bed space at the health care facility that could quickly be converted to inpatient or resident care to address the emergency.

(2) The applicant shall timely provide additional information requested by Commission staff.

C. Commission Action.

(1) The Executive Director may grant or deny an emergency CON application after consultation with the Chair of the Commission and receipt of suitably detailed information from the applicable State licensing agency regarding the need for emergency action. If, upon receipt of this information, the Executive Director agrees that the project is needed to address an emergency situation, the Executive Director shall issue an emergency Certificate of Need. The issuance of an emergency CON shall be on the agenda of the next scheduled Commission meeting for confirmation by the Commission.

(2) The Executive Director may exercise the discretion not to make a decision on an emergency CON application and refer the application for consideration by the Commission. If a quorum of the Commission agrees that the project is needed to address an emergency situation, the Commission shall issue an emergency Certificate of Need.

D. Duration of Emergency Certificate of Need. The emergency CON is temporary and is valid for a period not to exceed 165 days. The duration of an emergency CON may be extended by the Executive Director for good cause shown by the applicant or at the request of the Secretary.

E. A health care facility that desires to retain the capacity or project approved in an emergency CON shall, at least 30 days before the termination of the emergency CON, file a letter of intent followed by a CON application in accordance with the provisions in Regulation .08 of this chapter for an unscheduled review. The normal review process and time period set forth in this chapter apply to the review of a CON application filed after issuance of an emergency CON. This filing deadline may be extended by the Executive Director. The duration of an emergency CON shall be extended automatically during any period of time when the applicant has properly and timely sought a CON to retain the capacity or project approved on an emergency basis.

F. Review of Denied Application. In the event the Executive Director denies an application for an emergency CON, the applicant may submit a written request for Commission review of the decision within 15 days of the denial, stating with particularity the grounds and factual basis for the applicant's disagreement with the Executive Director's decision. The Commission shall make a decision on the request for review within 45 days of the request.

.21 Severability.

If any provision of this chapter is declared void by a court of law, the remainder of this chapter shall be unaffected and of continued force and effect.

.22 Effective Date.

A. A letter of intent or application submitted after the effective date of these regulations is subject to their provisions.

B. A request for a determination of coverage under Regulation .14A of this chapter, submitted after the effective date of these regulations, is subject to the provisions of this chapter.

C. Upon request by a holder, a project that has previously received a Certificate of Need or other Commission approval may be governed by this chapter.

D. Pending Reviews.

(1) Except in contested or comparative CON reviews, an application for a CON or other Commission approval pending at the time these regulations become effective shall be subject to their provision upon request of the applicant.

(2) Upon request of an applicant for a CON in a contested or comparative review, an application pending at the time these regulations become effective may be subject to their provisions with the consent of all interested parties and upon a finding of good cause by the reviewer.

(3) If the applicable CON review criteria have materially changed as a result of these regulations, the application of these regulations to a pending CON application shall be deemed a modification and governed by Regulation .08E of this chapter.

RANDOLPH S. SERGENT
Chair
Maryland Health Care Commission