Title 10 MARYLAND DEPARTMENT OF HEALTH

Subtitle 24 MARYLAND HEALTH CARE COMMISSION

Chapter 01 Procedural Regulations for Health Care Facilities and Services

Authority: Health-General Article, §§19-109(a)(1) and (8), 19-116(b), 19-118(d), 19-120, 19-120.1, 19-120.2 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) "Comprehensive care facility" means a nursing home as defined at §19-1401, Health-General, Annotated Code of Maryland.

(18) "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.

(19) "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.

(20) "Contested review" means a review in which a person has been recognized as an interested party.

(21) "Department" means the Maryland Department of Health.

(22) "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.

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

(24) "Existing health care facility" means a health care facility that is licensed by the Department.

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

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

(27) 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.

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

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

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

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

(32) "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.

(33) 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.

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

(35) "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.

(36) "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.

(37) "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.

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

(39) 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.

(40) "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.

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

(42) "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.

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

(44) "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.

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

(46) "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.

(47) "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.

(48) "Nursing home" has the meaning stated at §19-1401, Health-General, Annotated Code of Maryland.

(49) "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.

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

(51) "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.

(52) "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.

(53) "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.

(54) 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.

(55) 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.

(56) "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.

(57) 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.

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

(59) "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.

(60) "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.

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

(62) "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.

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

(64) "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.

(65) "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.

.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;

(d) A description of any conditions imposed by the Commission on the facility and an affirmation that the person acquiring the facility will abide by any conditions still in effect; and

(e) 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 nursing home , 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.

(5) Conditions imposed by the Commission on a health care facility survive an acquisition of the facility.

B. Acquisition of a Nursing Home, Home Health Agency, or Hospice.

(1) In addition to providing the information required in §A of this regulation, a person seeking to acquire a nursing home shall obtain approval for the acquisition in accordance with Regulation .21 of this chapter.

(2) In addition to providing the information required in §A, a person seeking to acquire a 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.

(3) Disqualification for Acquisition. A nursing home, 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.

(4) 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, a 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) Temporary Delicensure of Nursing Home Bed Capacity after an Acquisition

(a) A temporary delicensure of licensed bed capacity or a licensed and operating nursing home following an acquisition does not require CON review, and the Commission will retain the bed capacity or the nursing home on its inventory for up to three years immediately following the acquisition, if the person who acquired the nursing home:

(i) Provides written notice to the Commission at least 30 days before the proposed temporary delicensure;

(ii) Demonstrates the temporary delicensure is needed to reduce the number of resident rooms that contain more than two beds;

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

(iv) Has received authorization from the Executive Director for the temporary delicensure.

(b) The Executive Director may extend the period of a temporary delicensure under this subsection beyond three years for good cause including:

(i) Demonstrated progress toward eliminating multi-bedded rooms by expanding the existing facility;

(ii) A pending or approved application for a CON or exemption from CON review to relocate the beds to another existing or new facility;

(iii) Evidence of physical or legal constraints; or

(iv) Evidence of good faith negotiations to sell the beds.

(3) 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.

(4) 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.

(5) 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.

(6) 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.

(7) 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.

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

(9) 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.

(10) 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.

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.

.12 Holder Responsibilities and Penalties for Noncompliance .

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. Enforcement. The Commission may impose financial penalties, withdraw a CON or other Commission approval, or both, if it finds that:

(1) The person who obtained Commission approval made a material misrepresentation upon which the Commission relied in approving the application or issuing first use approval;

(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 person who obtained Commission approval 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;

(6) The project differs materially from that approved by the Commission, including failure to timely seek approval of a project change in accordance with Regulation .17 of this chapter; or

(7) The holder failed to obtain approval under Regulation .18 of this chapter prior to first use of any portion of a facility or service developed under a CON or other Commission approval.

F. Financial Penalties.

(1) Financial penalties imposed in accordance with this regulation may not exceed:

(a) $100 per day for each day the violation continues for failure to timely provide a semiannual progress report; or

(b) 1 percent of the approved budget for any other violation.

(2) The Commission shall consider the following factors in determining the amount of any financial penalty:

(a) The willfulness of the improper conduct;

(b) The extent of actual or potential public harm caused by the violation;

(c) The cost of investigation;

(d) The holder's prior record of compliance;

(e) The budget approved in the CON or other Commission approval;

(f) The holder's ability to pay; and

(g) If applicable, the amount of any unapproved capital cost increase that exceeds the approved budget.

G. Notice Before Enforcement Action.

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

(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 or financial penalties should not be imposed.

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

H. Final action by the Commission imposing financial penalties or 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.

I. 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

.21 Acquisition of Nursing Homes

A. Notice of Transfers of Ownership

(1) A person shall provide notice to the Commission at least 30 days before the change of ownership of a nursing home, including changes in ownership of real property and improvements, bed rights, or operatorship, that:

(a) Involves at least a 5% transfer in ownership interest; and

(b) Is not an acquisition that requires approval under §B of this regulation.

(2) The notice required by §A(1) of this regulation shall be in a form required by the Commission and include:

(a) A description of the change in ownership interest;

(b) Complete organizational charts for all persons holding at least a 5% ownership interest in the nursing home prior to and following the proposed transfer;

(c) An attestation that the change does not require approval under §B of this regulation; and

(d) Any other information requested by the Commission.

B. Request for Acquisition Approval

(1) Applicability.

(a) This section does not apply to an acquisition that involves only changes of ownership interests among existing owners of a nursing home.

(b) This section applies to:

(i) Transfers of stock or assets of the owner of the real property and improvements, bed rights, or operation of the nursing home, or any combination thereof;

(ii) An affiliation agreement between non-profit entities that changes the person who controls a nursing home's operation or assets; and

(iii) A lease agreement that changes the person who controls a nursing home's operation or assets.

(2) At least 60 days before closing on an acquisition of a nursing home, a person shall:

(a) Submit to the Commission a request for acquisition approval in a form prescribed by the Commission; and

(b) Provide notice, in the form prescribed by the Commission, to the residents, resident representatives, and employees of the nursing home that:

(i) The request for acquisition was submitted to the Commission; and

(ii) They have the right to submit comments.

(3) Notice by the Commission to the Public, and Other State Agencies. Within 5 days after it receives a complete Request for Acquisition Approval, the Commission shall:

(a) Submit notice of its receipt and the deadline for residents, resident representatives and employees of the nursing home to submit comments on the proposed acquisition:

(i) To at least one newspaper of general circulation in the affected area;

(ii) To be published in the next available issue of the Maryland Register; and

(iii) On the Commission's website; and

(b) Provide notice of the request to:

(i) The Secretary or the Secretary's designee;

(ii) The Office of the Attorney General;

(iii) The Secretary of Aging; and

(iv) The State Long-Term Care Ombudsman Program.

C. Executive Director Action

(1) The Executive Director shall review a Request for Acquisition Approval within 45 days after receiving the completed request from the applicant.

(2) The Executive Director, in consultation with the Secretary or the Secretary's designee, may:

(a) Approve the acquisition;

(b) Approve the acquisition with conditions;

(c) Deny the acquisition; or

(d) Refer the Request for Acquisition Approval to the Commission for a final decision.

(3) To approve a request for acquisition approval, the Executive Director must find that the acquisition:

(a) Is consistent with COMAR 10.24.20, the State Health Plan chapter for Comprehensive Care Facility (Nursing Home) Services; and

(b) Is in the public interest.

(4) In determining whether an acquisition of a nursing home is in the public interest, the Executive Director shall:

(a) Consider comments from individuals who:

(i) Reside in the nursing home;

(ii) Have family members who reside in the nursing home; or

(iii) Are employed as employees of the nursing home; and

(b) Consult with the Attorney General on whether the acquisition raises public interest concerns.

D. Commission Action. If the Executive Director refers a Request for Acquisition Approval to the Commission under §C(2)(iv) of this regulation, the Commission shall use the criteria specified in §C(3) and (4) of this regulation to make a final decision within 60 days after receiving the completed request from the applicant.

E. The Commission shall promptly send a copy of the decision of the Executive Director or Commission on a Request for Acquisition Approval to the Secretary, the Secretary of Aging, the Office of Health Care Quality, and the Office of the Attorney General, and the State Long–Term Care Ombudsman.

F. Appeal.

(1) Commission Review of Executive Director Decision.

(a) A person who is a party to the acquisition may seek Commission review of an Executive Director's decision denying the request or imposing a condition on approval.

(b) A request for review of an Executive Director's decision:

(i) Shall be filed within 15 days after the issuance of a decision;

(ii) Shall specifically identify each finding and conclusion to which review is requested; and

(iii) May include a request for oral argument.

(c) The Commission shall review the Executive Director's decision within 45 days of the request for review.

(2) Judicial Review.

(a) A decision of the Commission under §D or §E(1) of this regulation shall be a final decision for the purpose of judicial review.

(b) A person that is a party to the acquisition may take a direct judicial appeal within 30 days after the Commission makes the final decision.

G. Annual Reports.

(1) On or before July 1 immediately following the acquisition of a nursing home and each year for 3 years thereafter, the person that acquired the nursing home shall submit a report to the Commission in accordance with COMAR 10.24.20.

(2) The Commission shall provide a copy of the report required under §G(1) of this regulation to the Secretary, the Secretary of Aging, the Office of Health Care Quality, the Office of the Attorney General, and the State Long–Term Care Ombudsman.

.22 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.

.23 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.