Certificate of Need Law
Chapter 408, Sections 408.031 – 408.0455
Florida Statutes (2011)

PART I
HEALTH FACILITY AND SERVICES PLANNING
(ss. 408.031-408.7071)

408.031 Short title.—Sections 408.031-408.045 shall be known and may be cited as the "Health Facility and Services Development Act."

History.—s. 18, ch. 87-92; s. 15, ch. 92-33; s. 7, ch. 95-144. Note.—Former s. 381.701.

408.032 Definitions relating to Health Facility and Services Development Act.—As used in ss. 408.031-408.045, the term:

(1) "Agency" means the Agency for Health Care Administration.

(2) "Capital expenditure" means an expenditure, including an expenditure for a construction project undertaken by a health care facility as its own contractor, which, under generally accepted accounting principles, is not properly chargeable as an expense of operation and maintenance, which is made to change the bed capacity of the facility, or substantially change the services or service area of the health care facility, health service provider, or hospice, and which includes the cost of the studies, surveys, designs, plans, working drawings, specifications, initial financing costs, and other activities essential to acquisition, improvement, expansion, or replacement of the plant and equipment.

(3) "Certificate of need" means a written statement issued by the agency evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility, health service, or hospice.

(4) "Commenced construction" means initiation of and continuous activities beyond site preparation associated with erecting or modifying a health care facility, including procurement of a building permit applying the use of agency-approved construction documents, proof of an executed owner/contractor agreement or an irrevocable or binding forced account, and actual undertaking of foundation forming with steel installation and concrete placing.

(5) "District" means a health service planning district composed of the following counties:

District 1.—Escambia, Santa Rosa, Okaloosa, and Walton Counties.
District 2.—Holmes, Washington, Bay, Jackson, Franklin, Gulf, Gadsden, Liberty, Calhoun, Leon, Wakulla, Jefferson, Madison, and Taylor Counties.
District 3.—Hamilton, Suwannee, Lafayette, Dixie, Columbia, Gilchrist, Levy, Union, Bradford, Putnam, Alachua, Marion, Citrus, Hernando, Sumter, and Lake Counties.

District 4.—Baker, Nassau, Duval, Clay, St. Johns, Flagler, and Volusia Counties.
District 5.—Pasco and Pinellas Counties.
District 6.—Hillsborough, Manatee, Polk, Hardee, and Highlands Counties.
District 7.—Seminole, Orange, Osceola, and Brevard Counties.
District 8.—Sarasota, DeSoto, Charlotte, Lee, Glades, Hendry, and Collier Counties.
District 9.—Indian River, Okeechobee, St. Lucie, Martin, and Palm Beach Counties.
District 10.—Broward County.
District 11.—Miami-Dade and Monroe Counties.

(6) "Exemption" means the process by which a proposal that would otherwise require a certificate of need may proceed without a certificate of need.

(7) "Expedited review" means the process by which certain types of applications are not subject to the review cycle requirements contained in s. 408.039(1), and the letter of intent requirements contained in s. 408.039(2).

(8) "Health care facility" means a hospital, long-term care hospital, skilled nursing facility, hospice, or intermediate care facility for the developmentally disabled. A facility relying solely on spiritual means through prayer for healing is not included as a health care facility.

(9) "Health services" means inpatient diagnostic, curative, or comprehensive medical rehabilitative services and includes mental health services. Obstetric services are not health services for purposes of ss. 408.031-408.045.

(10) "Hospice" or "hospice program" means a hospice as defined in part IV of chapter 400.

(11) "Hospital" means a health care facility licensed under chapter 395.

(12) "Intermediate care facility for the developmentally disabled" means a residential facility licensed under chapter 393 and certified by the Federal Government pursuant to the Social Security Act as a provider of Medicaid services to persons who are mentally retarded or who have a related condition.

(13) "Long-term care hospital" means a hospital licensed under chapter 395 which meets the requirements of 42 C.F.R. s. 412.23(e) and seeks exclusion from the acute care Medicare prospective payment system for inpatient hospital services.

(14) "Mental health services" means inpatient services provided in a hospital licensed under chapter 395 and listed on the hospital license as psychiatric beds for adults; psychiatric beds for children and adolescents; intensive residential treatment beds for children and adolescents; substance abuse beds for adults; or substance abuse beds for children and adolescents.

(15) "Nursing home geographically underserved area" means:
- (a) A county in which there is no existing or approved nursing home;
- (b) An area with a radius of at least 20 miles in which there is no existing or approved nursing home; or
- (c) An area with a radius of at least 20 miles in which all existing nursing homes have maintained at least a 95 percent occupancy rate for the most recent 6 months or a 90 percent occupancy rate for the most recent 12 months.

(16) "Skilled nursing facility" means an institution, or a distinct part of an institution, which is primarily engaged in providing, to inpatients, skilled nursing care and related services for patients who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons.

(17) "Tertiary health service" means a health service which, due to its high level of intensity, complexity, specialized or limited applicability, and cost, should be limited to, and concentrated in, a limited number of hospitals to ensure the quality, availability, and cost-effectiveness of such service. Examples of such service include, but are not limited to, pediatric cardiac catheterization, pediatric open-heart surgery, organ transplantation, neonatal intensive care units, comprehensive rehabilitation, and medical or surgical services which are experimental or developmental in nature to the extent that the provision of such services is not yet contemplated within the commonly accepted course of diagnosis or treatment for the condition addressed by a given service. The agency shall establish by rule a list of all tertiary health services.

History.—s. 19, ch. 87-92; s. 19, ch. 88-294; s. 2, ch. 89-308; s. 7, ch. 89-354; s. 21, ch. 91-158; s. 54, ch. 91-221; s. 1, ch. 91-282; ss. 15, 16, ch. 92-33; s. 10, ch. 92-58; s. 22, ch. 93-214; s. 8, ch. 95-144; s. 28, ch. 95-210; s. 2, ch. 95-394; s. 1, ch. 97-270; s. 3, ch. 2000-256; s. 4, ch. 2000-318; s. 2, ch. 2004-383; s. 74, ch. 2006-197; s. 111, ch. 2008-4.
Note.—Former s. 381.702.

408.033 Local and state health planning.—

(1) LOCAL HEALTH COUNCILS.—

- (a) Local health councils are hereby established as public or private nonprofit agencies serving the counties of a district. The members of each council shall be appointed in an equitable manner by the county commissions having jurisdiction in the respective district. Each council shall be composed of a number of

persons equal to 11/2 times the number of counties which compose the district or 12 members, whichever is greater. Each county in a district shall be entitled to at least one member on the council. The balance of the membership of the council shall be allocated among the counties of the district on the basis of population rounded to the nearest whole number; except that in a district composed of only two counties, no county shall have fewer than four members. The appointees shall be representatives of health care providers, health care purchasers, and nongovernmental health care consumers, but not excluding elected government officials. The members of the consumer group shall include a representative number of persons over 60 years of age. A majority of council members shall consist of health care purchasers and health care consumers. The local health council shall provide each county commission a schedule for appointing council members to ensure that council membership complies with the requirements of this paragraph. The members of the local health council shall elect a chair. Members shall serve for terms of 2 years and may be eligible for reappointment.

(b) Each local health council may:

1. Develop a district area health plan that permits each local health council to develop strategies and set priorities for implementation based on its unique local health needs.
2. Advise the agency on health care issues and resource allocations.
3. Promote public awareness of community health needs, emphasizing health promotion and cost-effective health service selection.
4. Collect data and conduct analyses and studies related to health care needs of the district, including the needs of medically indigent persons, and assist the agency and other state agencies in carrying out data collection activities that relate to the functions in this subsection.
5. Monitor the onsite construction progress, if any, of certificate-of-need approved projects and report council findings to the agency on forms provided by the agency.
6. Advise and assist any regional planning councils within each district that have elected to address health issues in their strategic regional policy plans with the development of the health element of the plans to address the health goals and policies in the State Comprehensive Plan.
7. Advise and assist local governments within each district on the development of an optional health plan element of the comprehensive plan provided in chapter 163, to assure compatibility with the health goals and policies in the State Comprehensive Plan and district health plan. To facilitate the implementation of this section, the local health council shall annually provide the local governments in its service area, upon request, with:
    a. A copy and appropriate updates of the district health plan;
    b. A report of hospital and nursing home utilization statistics for facilities within the local government jurisdiction; and
    c. Applicable agency rules and calculated need methodologies for health facilities and services regulated under s. 408.034 for the district served by the local health council.
8. Monitor and evaluate the adequacy, appropriateness, and effectiveness, within the district, of local, state, federal, and private funds distributed to meet the needs of the medically indigent and other underserved population groups.
9. In conjunction with the Department of Health, plan for services at the local level for persons infected with the human immunodeficiency virus.
10. Provide technical assistance to encourage and support activities by providers, purchasers, consumers, and local, regional, and state agencies in meeting the health care goals, objectives, and policies adopted by the local health council.
11. Provide the agency with data required by rule for the review of certificate-of-need applications and the projection of need for health services and facilities in the district.

(c) Local health councils may conduct public hearings pursuant to s. 408.039(3)(b).

(d) Each local health council shall enter into a memorandum of agreement with each regional planning council in its district that elects to address health issues in its strategic regional policy plan. In addition, each local health council shall enter into a memorandum of agreement with each local government that includes an optional health element in its comprehensive plan. Each memorandum of agreement must specify the manner in which each local government, regional planning council, and local health council will coordinate its activities to ensure a unified approach to health planning and implementation efforts.

(e) Local health councils may employ personnel or contract for staffing services with persons who possess appropriate qualifications to carry out the councils' purposes. However, such personnel are not state employees.

(f) Personnel of the local health councils shall provide an annual orientation to council members about council member responsibilities.

(g) Each local health council may accept and receive, in furtherance of its health planning functions, funds, grants, and services from governmental agencies and from private or civic sources and to perform studies related to local health planning in exchange for such funds, grants, or services. Each council shall, no later than January 30 of each year, render an accounting of the receipt and disbursement of such funds received by it to the Department of Health.

(2) FUNDING.—

(a) The Legislature intends that the cost of local health councils be borne by assessments on selected health care facilities subject to facility licensure by the Agency for Health Care Administration, including abortion clinics, assisted living facilities, ambulatory surgical centers, birthing centers, clinical laboratories except community nonprofit blood banks and clinical laboratories operated by practitioners for exclusive use regulated under s. 483.035, home health agencies, hospices, hospitals, intermediate care facilities for the developmentally disabled, nursing homes, health care clinics, and multiphasic testing centers and by assessments on organizations subject to certification by the agency pursuant to chapter 641, part III, including health maintenance organizations and prepaid health clinics.

(b) 1. A hospital licensed under chapter 395, a nursing home licensed under chapter 400, and an assisted living facility licensed under chapter 429 shall be assessed an annual fee based on number of beds.

2. All other facilities and organizations listed in paragraph (a) shall each be assessed an annual fee of $150.

3. Facilities operated by the Department of Children and Family Services, the Department of Health, or the Department of Corrections and any hospital which meets the definition of rural hospital pursuant to s. 395.602 are exempt from the assessment required in this subsection.

(c) 1. The agency shall, by rule, establish fees for hospitals and nursing homes based on an assessment of $2 per bed. However, no such facility shall be assessed more than a total of $500 under this subsection.

2. The agency shall, by rule, establish fees for assisted living facilities based on an assessment of $1 per bed. However, no such facility shall be assessed more than a total of $150 under this subsection.

3. The agency shall, by rule, establish an annual fee of $150 for all other facilities and organizations listed in paragraph (a).

(d) The agency shall, by rule, establish a facility billing and collection process for the billing and collection of the health facility fees authorized by this subsection.

(e) A health facility which is assessed a fee under this subsection is subject to a fine of $100 per day for each day in which the facility is late in submitting its annual fee up to the maximum of the annual fee owed by the facility. A facility which refuses to pay the fee or fine is subject to the forfeiture of its license.

(f) The agency shall deposit in the Health Care Trust Fund all health care facility assessments that are assessed under this subsection and shall transfer such funds to the Department of Health for funding of the local health councils. The remaining certificate-of-need application fees shall be used only for the purpose of administering the certificate-of-need program.

(3) DUTIES AND RESPONSIBILITIES OF THE AGENCY.—

(a) The agency is responsible for the coordinated planning of health care services in the state.

(b) The agency shall develop and maintain a comprehensive health care database for the purpose of health planning and for certificate-of-need determinations. The agency or its contractor is authorized to require the submission of information from health facilities, health service providers, and licensed health professionals which is determined by the agency, through rule, to be necessary for meeting the agency's responsibilities as established in this section.

(c) The Department of Health shall contract with the local health councils for the services specified in subsection (1). All contract funds shall be distributed according to an allocation plan developed by the department. The department may withhold funds from a local health council or cancel its contract with a local health council which does not meet performance standards agreed upon by the department and local health councils.

History.—s. 20, ch. 87-92; s. 40, ch. 88-380; s. 35, ch. 88-394; s. 1, ch. 89-104; s. 24, ch. 89-294; s. 2, ch. 89-296; s. 15, ch. 89-527; s. 2, ch. 91-48; s. 22, ch. 91-158; ss. 2, 104, ch. 91-282; s. 5, ch. 91-429; ss. 15, 17, ch. 92-33; s. 2, ch. 92-174; s. 66, ch. 92-289; s. 22, ch. 93-120; s. 11, ch. 93-129; s. 33, ch. 93-206; s. 8, ch. 93-267; s. 9, ch. 95-144; s. 29, ch. 95-210; s. 3, ch. 95-394; s. 11, ch. 97-79; s. 1, ch. 97-91; s. 35, ch. 97-103; s. 62, ch. 97-237; s. 175, ch. 99-8; s. 4, ch. 2000-256; s. 5, ch. 2000-318; s. 3, ch. 2004-383; s. 75, ch. 2006-197; s. 114, ch. 2010-102.

Note.—Former s. 381.703.

408.034 Duties and responsibilities of agency; rules.—

(1) The agency is designated as the single state agency to issue, revoke, or deny certificates of need and to issue, revoke, or deny exemptions from certificate-of-need review in accordance with present and future federal and state statutes. The agency is designated as the state health planning agency for purposes of federal law.

(2) In the exercise of its authority to issue licenses to health care facilities and health service providers, as provided under chapters 393 and 395 and parts II and IV of chapter 400, the agency may not issue a license to any health care facility or health service provider that fails to receive a certificate of need or an exemption for the licensed facility or service.

(3) The agency shall establish, by rule, uniform need methodologies for health services and health facilities. In developing uniform need methodologies, the agency shall, at a minimum, consider the demographic characteristics of the population, the health status of the population, service use patterns, standards and trends, geographic accessibility, and market economics.

(4) Prior to determining that there is a need for additional community nursing facility beds in any area of the state, the agency shall determine that the need cannot be met through the provision, enhancement, or expansion of home and community-based services. In determining such need, the agency shall examine nursing home placement patterns and demographic patterns of persons entering nursing homes and the availability of and effectiveness of existing home-based and community-based service delivery systems at meeting the long-term care needs of the population. The agency shall recommend to the Legislature changes that could be made to existing home-based and community-based delivery systems to lessen the need for additional nursing facility beds.

(5) The agency shall establish by rule a nursing-home-bed-need methodology that has a goal of maintaining a subdistrict average occupancy rate of 94 percent and that reduces the community nursing home bed need for the areas of the state where the agency establishes pilot community diversion programs through the Title XIX aging waiver program.

(6) The agency may adopt rules necessary to implement ss. 408.031-408.045.

History.—s. 21, ch. 87-92; s. 8, ch. 89-354; s. 1, ch. 91-263; s. 15, ch. 92-33; s. 18, ch. 93-214; s. 10, ch. 95-144; s. 2, ch. 98-85; s. 5, ch. 2000-256; s. 6, ch. 2000-318; s. 13, ch. 2002-223; s. 9, ch. 2004-298; s. 4, ch. 2004-383; s. 3, ch. 2005-60; s. 76, ch. 2006-197.
Note.—Former s. 381.704.

408.035 Review criteria.—

(1) The agency shall determine the reviewability of applications and shall review applications for certificate-of-need determinations for health care facilities and health services in context with the following criteria, except for general hospitals as defined in s. 395.002:
   (a) The need for the health care facilities and health services being proposed.
   (b) The availability, quality of care, accessibility, and extent of utilization of existing health care facilities and health services in the service district of the applicant.
   (c) The ability of the applicant to provide quality of care and the applicant's record of providing quality of care.
   (d) The availability of resources, including health personnel, management personnel, and funds for capital and operating expenditures, for project accomplishment and operation.
   (e) The extent to which the proposed services will enhance access to health care for residents of the service district.
   (f) The immediate and long-term financial feasibility of the proposal.
   (g) The extent to which the proposal will foster competition that promotes quality and cost-effectiveness.
   (h) The costs and methods of the proposed construction, including the costs and methods of energy provision and the availability of alternative, less costly, or more effective methods of construction.
   (i) The applicant's past and proposed provision of health care services to Medicaid patients and the medically indigent.
   (j) The applicant's designation as a Gold Seal Program nursing facility pursuant to s. 400.235, when the applicant is requesting additional nursing home beds at that facility.

(2) For a general hospital, the agency shall consider only the criteria specified in paragraph (1)(a), paragraph (1)(b), except for quality of care in paragraph (1)(b), and paragraphs (1)(e), (g), and (i).

History.—s. 22, ch. 87-92; s. 20, ch. 88-294; s. 15, ch. 92-33; ss. 37, 50, ch. 93-217; s. 30, ch. 95-210; s. 36, ch. 97-103; s. 39, ch. 97-264; s. 2, ch. 97-270; s. 20, ch. 99-394; s. 6, ch. 2000-256; s. 7, ch. 2000-318; s. 5, ch. 2004-383; s. 1, ch. 2008-29.
Note.—Former s. 381.705.

408.036 Projects subject to review; exemptions.—

(1) APPLICABILITY.—Unless exempt under subsection (3), all health-care-related projects, as described in paragraphs (a)-(g), are subject to review and must file an application for a certificate of need with the agency. The agency is exclusively responsible for determining whether a health-care-related project is subject to review under ss. 408.031-408.045.

(a) The addition of beds in community nursing homes or intermediate care facilities for the developmentally disabled by new construction or alteration.

(b) The new construction or establishment of additional health care facilities, including a replacement health care facility when the proposed project site is not located on the same site as or within 1 mile of the existing health care facility, if the number of beds in each licensed bed category will not increase.

(c) The conversion from one type of health care facility to another, including the conversion from a general hospital, a specialty hospital, or a long-term care hospital.

(d) The establishment of a hospice or hospice inpatient facility, except as provided in s. 408.043.

(e) An increase in the number of beds for comprehensive rehabilitation.

(f) The establishment of tertiary health services, including inpatient comprehensive rehabilitation services.

(2) PROJECTS SUBJECT TO EXPEDITED REVIEW.—Unless exempt pursuant to subsection (3), projects subject to an expedited review shall include, but not be limited to:

(a) A transfer of a certificate of need, except that when an existing hospital is acquired by a purchaser, all certificates of need issued to the hospital which are not yet operational shall be acquired by the purchaser, without need for a transfer.

(b) Replacement of a nursing home within the same district, if the proposed project site is located within a geographic area that contains at least 65 percent of the facility's current residents and is within a 30-mile radius of the replaced nursing home.

(c) Relocation of a portion of a nursing home's licensed beds to a facility within the same district, if the relocation is within a 30-mile radius of the existing facility and the total number of nursing home beds in the district does not increase.

The agency shall develop rules to implement the provisions for expedited review, including time schedule, application content which may be reduced from the full requirements of s. 408.037(1), and application processing.

(3) EXEMPTIONS.—Upon request, the following projects are subject to exemption from the provisions of subsection (1):

(a) For hospice services or for swing beds in a rural hospital, as defined in s. 395.602, in a number that does not exceed one-half of its licensed beds.

(b) For the conversion of licensed acute care hospital beds to Medicare and Medicaid certified skilled nursing beds in a rural hospital, as defined in s. 395.602, so long as the conversion of the beds does not involve the construction of new facilities. The total number of skilled nursing beds, including swing beds, may not exceed one-half of the total number of licensed beds in the rural hospital as of July 1, 1993. Certified skilled nursing beds designated under this paragraph, excluding swing beds, shall be included in the community nursing home bed inventory. A rural hospital that subsequently decertifies any acute care beds exempted under this paragraph shall notify the agency of the decertification, and the agency shall adjust the community nursing home bed inventory accordingly.

(c) For the addition of nursing home beds at a skilled nursing facility that is part of a retirement community that provides a variety of residential settings and supportive services and that has been incorporated and operated in this state for at least 65 years on or before July 1, 1994. All nursing home beds must not be available to the public but must be for the exclusive use of the community residents.

(d) For an inmate health care facility built by or for the exclusive use of the Department of Corrections as provided in chapter 945. This exemption expires when such facility is converted to other uses.

(e) For mobile surgical facilities and related health care services provided under contract with the Department of Corrections or a private correctional facility operating pursuant to chapter 957.

(f) For the creation of a single nursing home within a district by combining licensed beds from two or more licensed nursing homes within such district, regardless of subdistrict boundaries, if 50 percent of the beds in the created nursing home are transferred from the only nursing home in a county and its utilization data demonstrate that it had an occupancy rate of less than 75 percent for the 12-month period ending 90 days before the request for the exemption. This paragraph is repealed upon the expiration of the moratorium established in s. 408.0435(1).

(g) For state veterans' nursing homes operated by or on behalf of the Florida Department of Veterans' Affairs in accordance with part II of chapter 296 for which at least 50 percent of the construction cost is federally funded and for which the Federal Government pays a per diem rate not to exceed one-half of the cost of the veterans' care in such state nursing homes. These beds shall not be included in the nursing home bed inventory.

(h) For combination within one nursing home facility of the beds or services authorized by two or more certificates of need issued in the same planning subdistrict. An exemption granted under this paragraph shall extend the validity period of the certificates of need to be consolidated by the length of the period beginning upon submission of the exemption request and ending with issuance of the exemption. The longest validity period among the certificates shall be applicable to each of the combined certificates.

(i) For division into two or more nursing home facilities of beds or services authorized by one certificate of need issued in the same planning subdistrict. An exemption granted under this paragraph shall extend the validity period of the certificate of need to be divided by the length of the period beginning upon submission of the exemption request and ending with issuance of the exemption.

(j) For the addition of hospital beds licensed under chapter 395 for comprehensive rehabilitation in a number that may not exceed 10 total beds or 10 percent of the licensed capacity, whichever is greater.
    1. In addition to any other documentation otherwise required by the agency, a request for exemption submitted under this paragraph must:
        a. Certify that the prior 12-month average occupancy rate for the licensed beds being expanded meets or exceeds 80 percent.
        b. Certify that the beds have been licensed and operational for at least 12 months.
    2. The timeframes and monitoring process specified in s. 408.040(2)(a)-(c) apply to any exemption issued under this paragraph.
    3. The agency shall count beds authorized under this paragraph as approved beds in the published inventory of hospital beds until the beds are licensed.

(k) For the addition of nursing home beds licensed under chapter 400 in a number not exceeding 10 total beds or 10 percent of the number of beds licensed in the facility being expanded, whichever is greater; or, for the addition of nursing home beds licensed under chapter 400 at a facility that has been designated as a Gold Seal nursing home under s. 400.235 in a number not exceeding 20 total beds or 10 percent of the number of licensed beds in the facility being expanded, whichever is greater.
    1. In addition to any other documentation required by the agency, a request for exemption submitted under this paragraph must:
        a. Certify that the facility has not had any class I or class II deficiencies within the 30 months preceding the request for addition.
        b. Certify that the prior 12-month average occupancy rate for the nursing home beds at the facility meets or exceeds 96 percent.
        c. Certify that any beds authorized for the facility under this paragraph before the date of the current request for an exemption have been licensed and operational for at least 12 months.
    2. The timeframes and monitoring process specified in s. 408.040(2)(a)-(c) apply to any exemption issued under this paragraph.
    3. The agency shall count beds authorized under this paragraph as approved beds in the published inventory of nursing home beds until the beds are licensed.

(l) For the establishment of:
    1. A Level II neonatal intensive care unit with at least 10 beds, upon documentation to the agency that the applicant hospital had a minimum of 1,500 births during the previous 12 months;
    2. A Level III neonatal intensive care unit with at least 15 beds, upon documentation to the agency that the applicant hospital has a Level II neonatal intensive care unit of at least 10 beds and had a minimum of 3,500 births during the previous 12 months; or
    3. A Level III neonatal intensive care unit with at least 5 beds, upon documentation to the agency that the applicant hospital is a verified trauma center pursuant to s. 395.4001(14), and has a Level II neonatal intensive care unit,if the applicant demonstrates that it meets the requirements for quality of care, nurse staffing, physician staffing, physical plant, equipment, emergency transportation, and data reporting found in agency certificate-of-need rules for Level II and Level III neonatal intensive care units and if the applicant commits to the provision of services to

Medicaid and charity patients at a level equal to or greater than the district average. Such a commitment is subject to s. 408.040.

(m) 1. For the provision of adult open-heart services in a hospital located within the boundaries of a health service planning district, as defined in s. 408.032(5), which has experienced an annual net out-migration of at least 600 open-heart-surgery cases for 3 consecutive years according to the most recent data reported to the agency, and the district's population per licensed and operational open-heart programs exceeds the state average of population per licensed and operational open-heart programs by at least 25 percent. All hospitals within a health service planning district which meet the criteria reference in sub-subparagraphs 2.a.-h. shall be eligible for this exemption on July 1, 2004, and shall receive the exemption upon filing for it and subject to the following:

1. A hospital that has received a notice of intent to grant a certificate of need or a final order of the agency granting a certificate of need for the establishment of an open-heart-surgery program is entitled to receive a letter of exemption for the establishment of an adult open-heart-surgery program upon filing a request for exemption and complying with the criteria enumerated in sub-subparagraphs 2.a.-h., and is entitled to immediately commence operation of the program.
2. An otherwise eligible hospital that has not received a notice of intent to grant a certificate of need or a final order of the agency granting a certificate of need for the establishment of an open-heart-surgery program is entitled to immediately receive a letter of exemption for the establishment of an adult open-heart-surgery program upon filing a request for exemption and complying with the criteria enumerated in sub-subparagraphs 2.a.-h., but is not entitled to commence operation of its program until December 31, 2006.

2. A hospital shall be exempt from the certificate-of-need review for the establishment of an open-heart-surgery program when the application for exemption submitted under this paragraph complies with the following criteria:

a. The applicant must certify that it will meet and continuously maintain the minimum licensure requirements adopted by the agency governing adult open-heart programs, including the most current guidelines of the American College of Cardiology and American Heart Association Guidelines for Adult Open Heart Programs.
b. The applicant must certify that it will maintain sufficient appropriate equipment and health personnel to ensure quality and safety.
c. The applicant must certify that it will maintain appropriate times of operation and protocols to ensure availability and appropriate referrals in the event of emergencies.
d. The applicant can demonstrate that it has discharged at least 300 inpatients with a principal diagnosis of ischemic heart disease for the most recent 12-month period as reported to the agency.
e. The applicant is a general acute care hospital that is in operation for 3 years or more.
f. The applicant is performing more than 300 diagnostic cardiac catheterization procedures per year, combined inpatient and outpatient.
g. The applicant's payor mix at a minimum reflects the community average for Medicaid, charity care, and self-pay patients or the applicant must certify that it will provide a minimum of 5 percent of Medicaid, charity care, and self-pay to open-heart-surgery patients.
h. If the applicant fails to meet the established criteria for open-heart programs or fails to reach 300 surgeries per year by the end of its third year of operation, it must show cause why its exemption should not be revoked.

3. By December 31, 2004, and annually thereafter, the agency shall submit a report to the Legislature providing information concerning the number of requests for exemption it has received under this paragraph during the calendar year and the number of exemptions it has granted or denied during the calendar year.

(n) For the provision of percutaneous coronary intervention for patients presenting with emergency myocardial infarctions in a hospital without an approved adult open-heart-surgery program. In addition to any other documentation required by the agency, a request for an exemption submitted under this paragraph must comply with the following:

1. The applicant must certify that it will meet and continuously maintain the requirements adopted by the agency for the provision of these services. These licensure requirements shall be adopted by rule pursuant to ss. 120.536(1) and 120.54 and must be consistent with the guidelines published by the American College of Cardiology and the American Heart Association for the

provision of percutaneous coronary interventions in hospitals without adult open-heart services. At a minimum, the rules shall require the following:

a. Cardiologists must be experienced interventionalists who have performed a minimum of 75 interventions within the previous 12 months.
b. The hospital must provide a minimum of 36 emergency interventions annually in order to continue to provide the service.
c. The hospital must offer sufficient physician, nursing, and laboratory staff to provide the services 24 hours a day, 7 days a week.
d. Nursing and technical staff must have demonstrated experience in handling acutely ill patients requiring intervention based on previous experience in dedicated interventional laboratories or surgical centers.
e. Cardiac care nursing staff must be adept in hemodynamic monitoring and Intra-aortic Balloon Pump (IABP) management.
f. Formalized written transfer agreements must be developed with a hospital with an adult open-heart-surgery program, and written transport protocols must be in place to ensure safe and efficient transfer of a patient within 60 minutes. Transfer and transport agreements must be 1reviewed and tested, with appropriate documentation maintained at least every 3 months.
g. Hospitals implementing the service must first undertake a training program of 3 to 6 months' duration, which includes establishing standards and testing logistics, creating quality assessment and error management practices, and formalizing patient-selection criteria.

2. The applicant must certify that it will use at all times the patient-selection criteria for the performance of primary angioplasty at hospitals without adult open-heart-surgery programs issued by the American College of Cardiology and the American Heart Association. At a minimum, these criteria would provide for the following:
    a. Avoidance of interventions in hemodynamically stable patients who have identified symptoms or medical histories.
    b. Transfer of patients who have a history of coronary disease and clinical presentation of hemodynamic instability.
3. The applicant must agree to submit a quarterly report to the agency detailing patient characteristics, treatment, and outcomes for all patients receiving emergency percutaneous coronary interventions pursuant to this paragraph. This report must be submitted within 15 days after the close of each calendar quarter.
4. The exemption provided by this paragraph does not apply unless the agency determines that the hospital has taken all necessary steps to be in compliance with all requirements of this paragraph, including the training program required under sub-subparagraph 1.g.
5. Failure of the hospital to continuously comply with the requirements of sub-subparagraphs 1.c.-f. and subparagraphs 2. and 3. will result in the immediate expiration of this exemption.
6. Failure of the hospital to meet the volume requirements of sub-subparagraphs 1.a. and b. within 18 months after the program begins offering the service will result in the immediate expiration of the exemption.

If the exemption for this service expires under subparagraph 5. or subparagraph 6., the agency may not grant another exemption for this service to the same hospital for 2 years and then only upon a showing that the hospital will remain in compliance with the requirements of this paragraph through a demonstration of corrections to the deficiencies that caused expiration of the exemption. Compliance with the requirements of this paragraph includes compliance with the rules adopted pursuant to this paragraph.

(o) For the addition of mental health services or beds if the applicant commits to providing services to Medicaid or charity care patients at a level equal to or greater than the district average. Such a commitment is subject to s. 408.040.
(p) For replacement of a licensed nursing home on the same site, or within 3 miles of the same site, if the number of licensed beds does not increase.
(q) For consolidation or combination of licensed nursing homes or transfer of beds between licensed nursing homes within the same planning subdistrict, by providers that operate multiple nursing homes within that

planning subdistrict, if there is no increase in the planning subdistrict total number of nursing home beds and the site of the relocation is not more than 30 miles from the original location.

(r) For beds in state mental health treatment facilities defined in s. 394.455 and state mental health forensic facilities operated under chapter 916.

(s) For beds in state developmental disabilities centers as defined in s. 393.063.

(4) REQUESTS FOR EXEMPTION.—A request for exemption under subsection (3) may be made at any time and is not subject to the batching requirements of this section. The request shall be supported by such documentation as the agency requires by rule. The agency shall assess a fee of $250 for each request for exemption submitted under subsection (3).

(5) NOTIFICATION.—Health care facilities and providers must provide to the agency notification of:

(a) Replacement of a health care facility when the proposed project site is located in the same district and on the existing site or within a 1-mile radius of the replaced health care facility, if the number and type of beds do not increase.

(b) The termination of a health care service, upon 30 days' written notice to the agency.

(c) The addition or delicensure of beds.

Notification under this subsection may be made by electronic, facsimile, or written means at any time before the described action has been taken.

History.—s. 23, ch. 87-92; s. 21, ch. 88-294; s. 2, ch. 89-527; ss. 3, 16, ch. 91-282; s. 15, ch. 92-33; s. 67, ch. 92-289; s. 30, ch. 93-129; s. 19, ch. 93-214; s. 38, ch. 93-217; ss. 3, 4, ch. 94-206; s. 58, ch. 95-144; s. 143, ch. 95-418; s. 3, ch. 97-270; s. 4, ch. 97-290; s. 3, ch. 98-14; s. 22, ch. 98-80; s. 3, ch. 98-85; s. 8, ch. 98-303; s. 7, ch. 2000-256; s. 15, ch. 2000-305; s. 8, ch. 2000-318; s. 15, ch. 2001-104; s. 13, ch. 2003-2; s. 1, ch. 2003-274; s. 1, ch. 2003-289; s. 10, ch. 2004-298; s. 1, ch. 2004-382; s. 6, ch. 2004-383; s. 2, ch. 2006-161; s. 8, ch. 2006-192; s. 26, ch. 2006-195; s. 51, ch. 2006-227; s. 88, ch. 2007-5; s. 15, ch. 2008-244; s. 11, ch. 2009-20; s. 19, ch. 2010-4; s. 1, ch. 2011-195.

1Note.—As amended by s. 1, ch. 2004-382. The amendment by s. 6, ch. 2004-383, used "received" instead of "reviewed."

Note.—Former s. 381.706.

408.0361 Cardiovascular services and burn unit licensure.—

(1) Each provider of diagnostic cardiac catheterization services shall comply with rules adopted by the agency that establish licensure standards governing the operation of adult inpatient diagnostic cardiac catheterization programs. The rules shall ensure that such programs:

(a) Comply with the most recent guidelines of the American College of Cardiology and American Heart Association Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories.

(b) Perform only adult inpatient diagnostic cardiac catheterization services and will not provide therapeutic cardiac catheterization or any other cardiology services.

(c) Maintain sufficient appropriate equipment and health care personnel to ensure quality and safety.

(d) Maintain appropriate times of operation and protocols to ensure availability and appropriate referrals in the event of emergencies.

(e) Demonstrate a plan to provide services to Medicaid and charity care patients.

(2) Each provider of adult cardiovascular services or operator of a burn unit shall comply with rules adopted by the agency that establish licensure standards that govern the provision of adult cardiovascular services or the operation of a burn unit. Such rules shall consider, at a minimum, staffing, equipment, physical plant, operating protocols, the provision of services to Medicaid and charity care patients, accreditation, licensure period and fees, and enforcement of minimum standards. The certificate-of-need rules for adult cardiovascular services and burn units in effect on June 30, 2004, are authorized pursuant to this subsection and shall remain in effect and shall be enforceable by the agency until the licensure rules are adopted. Existing providers and any provider with a notice of intent to grant a certificate of need or a final order of the agency granting a certificate of need for adult cardiovascular services or burn units shall be considered grandfathered and receive a license for their programs effective on the effective date of this act. The grandfathered licensure shall be for at least 3 years or until July 1, 2008, whichever is longer, but shall be required to meet licensure standards applicable to existing programs for every subsequent licensure period.

(3) In establishing rules for adult cardiovascular services, the agency shall include provisions that allow for:

(a) Establishment of two hospital program licensure levels: a Level I program authorizing the performance of adult percutaneous cardiac intervention without onsite cardiac surgery and a Level II program authorizing the performance of percutaneous cardiac intervention with onsite cardiac surgery.

(b) For a hospital seeking a Level I program, demonstration that, for the most recent 12-month period as reported to the agency, it has provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations or, for the most recent 12-month period, has discharged or transferred at least 300 inpatients with the principal diagnosis of ischemic heart disease and that it has a formalized, written transfer agreement with a hospital that has a Level II program, including written transport protocols to ensure safe and efficient transfer of a patient within 60 minutes.

(c) For a hospital seeking a Level II program, demonstration that, for the most recent 12-month period as reported to the agency, it has performed a minimum of 1,100 adult inpatient and outpatient cardiac catheterizations, of which at least 400 must be therapeutic catheterizations, or, for the most recent 12-month period, has discharged at least 800 patients with the principal diagnosis of ischemic heart disease.

(d) Compliance with the most recent guidelines of the American College of Cardiology and American Heart Association guidelines for staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety.

(e) Establishment of appropriate hours of operation and protocols to ensure availability and timely referral in the event of emergencies.

(f) Demonstration of a plan to provide services to Medicaid and charity care patients.

(4) In order to ensure continuity of available services, the holder of a certificate of need for a newly licensed hospital that meets the requirements of this subsection may apply for and shall be granted Level I program status regardless of whether rules relating to Level I programs have been adopted. To qualify for a Level I program under this subsection, a hospital seeking a Level I program must be a newly licensed hospital established pursuant to a certificate of need in a physical location previously licensed and operated as a hospital, the former hospital must have provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations for the most recent 12-month period as reported to the agency, and the newly licensed hospital must have a formalized, written transfer agreement with a hospital that has a Level II program, including written transport protocols to ensure safe and efficient transfer of a patient within 60 minutes. A hospital meeting the requirements of this subsection may apply for certification of Level I program status before taking possession of the physical location of the former hospital, and the effective date of Level I program status shall be concurrent with the effective date of the newly issued hospital license.

(5)

(a) The agency shall establish a technical advisory panel to develop procedures and standards for measuring outcomes of adult cardiovascular services. Members of the panel shall include representatives of the Florida Hospital Association, the Florida Society of Thoracic and Cardiovascular Surgeons, the Florida Chapter of the American College of Cardiology, and the Florida Chapter of the American Heart Association and others with experience in statistics and outcome measurement. Based on recommendations from the panel, the agency shall develop and adopt rules for the adult cardiovascular services that include at least the following:

1. A risk adjustment procedure that accounts for the variations in severity and case mix found in hospitals in this state.
2. Outcome standards specifying expected levels of performance in Level I and Level II adult cardiovascular services. Such standards may include, but shall not be limited to, in-hospital mortality, infection rates, nonfatal myocardial infarctions, length of stay, postoperative bleeds, and returns to surgery.
3. Specific steps to be taken by the agency and licensed hospitals that do not meet the outcome standards within specified time periods, including time periods for detailed case reviews and development and implementation of corrective action plans.

(b) Hospitals licensed for Level I or Level II adult cardiovascular services shall participate in clinical outcome reporting systems operated by the American College of Cardiology and the Society for Thoracic Surgeons.

History.—s. 5, ch. 99-356; s. 48, ch. 2001-62; s. 2, ch. 2004-382; s. 7, ch. 2004-383; s. 1, ch. 2007-214; s. 2, ch. 2007-248; s. 88, ch. 2010-5.

408.037 Application content.—

(1) Except as provided in subsection (2) for a general hospital, an application for a certificate of need must contain:

(a) A detailed description of the proposed project and statement of its purpose and need in relation to the district health plan.

(b) A statement of the financial resources needed by and available to the applicant to accomplish the proposed project. This statement must include:
1. A complete listing of all capital projects, including new health facility development projects and health facility acquisitions applied for, pending, approved, or underway in any state at the time of application, regardless of whether or not that state has a certificate-of-need program or a capital expenditure review program pursuant to s. 1122 of the Social Security Act. The agency may, by rule, require less-detailed information from major health care providers. This listing must include the applicant's actual or proposed financial commitment to those projects and an assessment of their impact on the applicant's ability to provide the proposed project.
2. A detailed listing of the needed capital expenditures, including sources of funds.
3. A detailed financial projection, including a statement of the projected revenue and expenses for the first 2 years of operation after completion of the proposed project. This statement must include a detailed evaluation of the impact of the proposed project on the cost of other services provided by the applicant.

(c) An audited financial statement of the applicant. In an application submitted by an existing health care facility, health maintenance organization, or hospice, financial condition documentation must include, but need not be limited to, a balance sheet and a profit-and-loss statement of the 2 previous fiscal years' operation.

(2) An application for a certificate of need for a general hospital must contain a detailed description of the proposed general hospital project and a statement of its purpose and the needs it will meet. The proposed project's location, as well as its primary and secondary service areas, must be identified by zip code. Primary service area is defined as the zip codes from which the applicant projects that it will draw 75 percent of its discharges. Secondary service area is defined as the zip codes from which the applicant projects that it will draw its remaining discharges. If, subsequent to issuance of a final order approving the certificate of need, the proposed location of the general hospital changes or the primary service area materially changes, the agency shall revoke the certificate of need. However, if the agency determines that such changes are deemed to enhance access to hospital services in the service district, the agency may permit such changes to occur. A party participating in the administrative hearing regarding the issuance of the certificate of need for a general hospital has standing to participate in any subsequent proceeding regarding the revocation of the certificate of need for a hospital for which the location has changed or for which the primary service area has materially changed. In addition, the application for the certificate of need for a general hospital must include a statement of intent that, if approved by final order of the agency, the applicant shall within 120 days after issuance of the final order or, if there is an appeal of the final order, within 120 days after the issuance of the court's mandate on appeal, furnish satisfactory proof of the applicant's financial ability to operate. The agency shall establish documentation requirements, to be completed by each applicant, which show anticipated provider revenues and expenditures, the basis for financing the anticipated cash-flow requirements of the provider, and an applicant's access to contingency financing. A party participating in the administrative hearing regarding the issuance of the certificate of need for a general hospital may provide written comments concerning the adequacy of the financial information provided, but such party does not have standing to participate in an administrative proceeding regarding proof of the applicant's financial ability to operate. The agency may require a licensee to provide proof of financial ability to operate at any time if there is evidence of financial instability, including, but not limited to, unpaid expenses necessary for the basic operations of the provider.

(3) The applicant must certify that it will license and operate the health care facility. For an existing health care facility, the applicant must be the licenseholder of the facility.

History.—s. 24, ch. 87-92; s. 15, ch. 92-33; s. 4, ch. 97-270; s. 8, ch. 2000-256; s. 9, ch. 2000-318; s. 2, ch. 2008-29.
Note.—Former s. 381.707.

408.038 Fees.—The agency shall assess fees on certificate-of-need applications. Such fees shall be for the purpose of funding the activities of the agency and shall be allocated as provided in s. 408.033. The fee shall be determined as follows:

(1) A minimum base fee of $10,000.

(2) In addition to the base fee of $10,000, 0.015 of each dollar of proposed expenditure, except that a fee may not exceed $50,000.

History.—s. 25, ch. 87-92; s. 2, ch. 89-104; s. 16, ch. 89-527; s. 4, ch. 91-282; s. 15, ch. 92-33; s. 11, ch. 95-144; s. 17, ch. 97-79; s. 9, ch. 2000-256; s. 10, ch. 2000-318; s. 8, ch. 2004-383.

Note.—Former s. 381.708.

408.039 Review process.—The review process for certificates of need shall be as follows:

(1) REVIEW CYCLES.—The agency by rule shall provide for applications to be submitted on a timetable or cycle basis; provide for review on a timely basis; and provide for all completed applications pertaining to similar types of services or facilities affecting the same service district to be considered in relation to each other no less often than annually.

(2) LETTERS OF INTENT.—

(a) At least 30 days prior to filing an application, a letter of intent shall be filed by the applicant with the agency, respecting the development of a proposal subject to review. No letter of intent is required for expedited projects as defined by rule by the agency.

(b) The agency shall provide a mechanism by which applications may be filed to compete with proposals described in filed letters of intent.

(c) Letters of intent must describe the proposal; specify the number of beds sought, if any; identify the services to be provided and the specific subdistrict location; and identify the applicant.

(d) Within 21 days after filing a letter of intent, the agency shall publish notice of the filing of letters of intent in the Florida Administrative Weekly and notice that, if requested, a public hearing shall be held at the local level within 21 days after the application is deemed complete. Notices under this paragraph must contain due dates applicable to the cycle for filing applications and for requesting a hearing.

(3) APPLICATION PROCESSING.—

(a) An applicant shall file an application with the agency and shall furnish a copy of the application to the agency. Within 15 days after the applicable application filing deadline established by agency rule, the staff of the agency shall determine if the application is complete. If the application is incomplete, the staff shall request specific information from the applicant necessary for the application to be complete; however, the staff may make only one such request. If the requested information is not filed with the agency within 21 days after the receipt of the staff's request, the application shall be deemed incomplete and deemed withdrawn from consideration.

(b) Upon the request of any applicant or substantially affected person within 14 days after notice that an application has been filed, a public hearing may be held at the agency's discretion if the agency determines that a proposed project involves issues of great local public interest. In such cases, the agency shall attend the public hearing. The public hearing shall allow applicants and other interested parties reasonable time to present their positions and to present rebuttal information. A recorded verbatim record of the hearing shall be maintained. The public hearing shall be held at the local level within 21 days after the application is deemed complete.

(c) Except for competing applicants, in order to be eligible to challenge the agency decision on a general hospital application under review pursuant to paragraph (5)(c), existing hospitals must submit a detailed written statement of opposition to the agency and to the applicant. The detailed written statement must be received by the agency and the applicant within 21 days after the general hospital application is deemed complete and made available to the public.

(d) In those cases where a written statement of opposition has been timely filed regarding a certificate of need application for a general hospital, the applicant for the general hospital may submit a written response to the agency. Such response must be received by the agency within 10 days of the written statement due date.

(4) STAFF RECOMMENDATIONS.—

(a) The agency's review of and final agency action on applications shall be in accordance with statutory criteria and the implementing administrative rules. In the application review process, the agency shall give a preference, as defined by rule of the agency, to an applicant which proposes to develop a nursing home in a nursing home geographically underserved area.

(b) Within 60 days after all the applications in a review cycle are determined to be complete, the agency shall issue its State Agency Action Report and Notice of Intent to grant a certificate of need for the project in its entirety, to grant a certificate of need for identifiable portions of the project, or to deny a certificate of need. The State Agency Action Report shall set forth in writing its findings of fact and determinations upon which its decision is based. If the agency intends to grant a certificate of need, the State Agency Action Report or the Notice of Intent shall also include any conditions which the agency intends to attach to the certificate of need. The agency shall designate by rule a senior staff person, other than the person who issues the final order, to issue State Agency Action Reports and Notices of Intent.

(c) The agency shall publish its proposed decision set forth in the Notice of Intent in the Florida Administrative Weekly within 14 days after the Notice of Intent is issued.

(d) If no administrative hearing is requested pursuant to subsection (5), the State Agency Action Report and the Notice of Intent shall become the final order of the agency. The agency shall provide a copy of the final order to the appropriate local health council.

(5) ADMINISTRATIVE HEARINGS.—

(a) Within 21 days after publication of notice of the State Agency Action Report and Notice of Intent, any person authorized under paragraph (c) to participate in a hearing may file a request for an administrative hearing; failure to file a request for hearing within 21 days of publication of notice shall constitute a waiver of any right to a hearing and a waiver of the right to contest the final decision of the agency. A copy of the request for hearing shall be served on the applicant.

(b) Hearings shall be held in Tallahassee unless the administrative law judge determines that changing the location will facilitate the proceedings. The agency shall assign proceedings requiring hearings to the Division of Administrative Hearings of the Department of Management Services within 10 days after the time has expired for requesting a hearing. Except upon unanimous consent of the parties or upon the granting by the administrative law judge of a motion of continuance, hearings shall commence within 60 days after the administrative law judge has been assigned. For an application for a general hospital, administrative hearings shall commence within 6 months after the administrative law judge has been assigned, and a continuance may not be granted absent a finding of extraordinary circumstances by the administrative law judge. All parties, except the agency, shall bear their own expense of preparing a transcript. In any application for a certificate of need which is referred to the Division of Administrative Hearings for hearing, the administrative law judge shall complete and submit to the parties a recommended order as provided in ss. 120.569 and 120.57. The recommended order shall be issued within 30 days after the receipt of the proposed recommended orders or the deadline for submission of such proposed recommended orders, whichever is earlier. The division shall adopt procedures for administrative hearings which shall maximize the use of stipulated facts and shall provide for the admission of prepared testimony.

(c) In administrative proceedings challenging the issuance or denial of a certificate of need, only applicants considered by the agency in the same batching cycle are entitled to a comparative hearing on their applications. Existing health care facilities may initiate or intervene in an administrative hearing upon a showing that an established program will be substantially affected by the issuance of any certificate of need, whether reviewed under s. 408.036(1) or (2), to a competing proposed facility or program within the same district. With respect to an application for a general hospital, competing applicants and only those existing hospitals that submitted a detailed written statement of opposition to an application as provided in this paragraph may initiate or intervene in an administrative hearing. Such challenges to a general hospital application shall be limited in scope to the issues raised in the detailed written statement of opposition that was provided to the agency. The administrative law judge may, upon a motion showing good cause, expand the scope of the issues to be heard at the hearing. Such motion shall include substantial and detailed facts and reasons for failure to include such issues in the original written statement of opposition.

(d) The applicant’s failure to strictly comply with the requirements of s. 408.037(1) or paragraph (2)(c) is not cause for dismissal of the application, unless the failure to comply impairs the fairness of the proceeding or affects the correctness of the action taken by the agency.

(e) The agency shall issue its final order within 45 days after receipt of the recommended order. If the agency fails to take action within such time, or as otherwise agreed to by the applicant and the agency, the applicant may take appropriate legal action to compel the agency to act. When making a determination on an application for a certificate of need, the agency is specifically exempt from the time limitations provided in s. 120.60(1).

(6) JUDICIAL REVIEW.—

(a) A party to an administrative hearing for an application for a certificate of need has the right, within not more than 30 days after the date of the final order, to seek judicial review in the District Court of Appeal pursuant to s. 120.68. The agency shall be a party in any such proceeding.

(b) In such judicial review, the court shall affirm the final order of the agency, unless the decision is arbitrary, capricious, or not in compliance with ss. 408.031-408.045.

(c) The court, in its discretion, may award reasonable attorney's fees and costs to the prevailing party if the court finds that there was a complete absence of a justiciable issue of law or fact raised by the losing party.

(d) The party appealing a final order that grants a general hospital certificate of need shall pay the appellee's attorney's fees and costs, in an amount up to $1 million, from the beginning of the original administrative action if the appealing party loses the appeal, subject to the following limitations and requirements:

1. The party appealing a final order must post a bond in the amount of $1 million in order to maintain the appeal.
2. Except as provided under s. 120.595(5), in no event shall the agency be held liable for any other party's attorney's fees or costs.

History.—s. 26, ch. 87-92; s. 9, ch. 89-354; s. 15, ch. 92-33; s. 125, ch. 92-279; s. 55, ch. 92-326; s. 12, ch. 95-144; s. 190, ch. 96-410; s. 18, ch. 97-79; s. 5, ch. 97-270; s. 10, ch. 2000-256; s. 11, ch. 2000-318; s. 9, ch. 2004-383; s. 3, ch. 2008-29.
Note.—Former s. 381.709.

408.040 Conditions and monitoring.—

(1)

(a) The agency may issue a certificate of need, or an exemption, predicated upon statements of intent expressed by an applicant in the application for a certificate of need or an exemption. Any conditions imposed on a certificate of need or an exemption based on such statements of intent shall be stated on the face of the certificate of need or in the exemption approval.

(b) The agency may consider, in addition to the other criteria specified in s. 408.035, a statement of intent by the applicant that a specified percentage of the annual patient days at the facility will be utilized by patients eligible for care under Title XIX of the Social Security Act. Any certificate of need issued to a nursing home in reliance upon an applicant's statements that a specified percentage of annual patient days will be utilized by residents eligible for care under Title XIX of the Social Security Act must include a statement that such certification is a condition of issuance of the certificate of need. The certificate-of-need program shall notify the Medicaid program office and the Department of Elderly Affairs when it imposes conditions as authorized in this paragraph in an area in which a community diversion pilot project is implemented. Effective July 1, 2012, the agency may not impose sanctions related to patient day utilization by patients eligible for care under Title XIX of the Social Security Act for nursing homes.

(c) A certificateholder or an exemption holder may apply to the agency for a modification of conditions imposed under paragraph (a) or paragraph (b). If the holder of a certificate of need or an exemption demonstrates good cause why the certificate or exemption should be modified, the agency shall reissue the certificate of need or exemption with such modifications as may be appropriate. The agency shall by rule define the factors constituting good cause for modification.

(d) If the holder of a certificate of need or an exemption fails to comply with a condition upon which the issuance of the certificate or exemption was predicated, the agency may assess an administrative fine against the certificateholder or exemption holder in an amount not to exceed $1,000 per failure per day. Failure to annually report compliance with any condition upon which the issuance of the certificate or exemption was predicated constitutes noncompliance. In assessing the penalty, the agency shall take into account as mitigation the degree of noncompliance. Proceeds of such penalties shall be deposited in the Public Medical Assistance Trust Fund.

(2) 1

(a) Unless the applicant has commenced construction, if the project provides for construction, unless the applicant has incurred an enforceable capital expenditure commitment for a project, if the project does not provide for construction, or unless subject to paragraph (b), a certificate of need shall terminate 18 months after the date of issuance, except a certificate of need of an entity which was issued on or before April 1, 2009, shall terminate 36 months after the date of issuance. The agency shall monitor the progress of the holder of the certificate of need in meeting the timetable for project development specified in the application, and may revoke the certificate of need, if the holder of the certificate is not meeting such timetable and is not making a good-faith effort, as defined by rule, to meet it.

(b) A certificate of need issued to an applicant holding a provisional certificate of authority under chapter 651 shall terminate 1 year after the applicant receives a valid certificate of authority from the Office of Insurance Regulation of the Financial Services Commission.

(c) The certificate-of-need validity period for a project shall be extended by the agency, to the extent that the applicant demonstrates to the satisfaction of the agency that good-faith commencement of the project is

being delayed by litigation or by governmental action or inaction with respect to regulations or permitting precluding commencement of the project.

History.—s. 27, ch. 87-92; s. 22, ch. 88-294; s. 15, ch. 92-33; s. 13, ch. 95-144; s. 6, ch. 97-270; s. 4, ch. 98-85; s. 11, ch. 2000-256; s. 12, ch. 2000-318; s. 434, ch. 2003-261; s. 10, ch. 2004-383; s. 3, ch. 2006-161; s. 2, ch. 2007-82; s. 4, ch. 2008-29; s. 1, ch. 2009-45; s. 14, ch. 2009-223; s. 3, ch. 2011-135.

1Note.—As amended by s. 14, ch. 2009-223. For a description of multiple acts in the same session affecting a statutory provision, see preface to the Florida Statutes, "Statutory Construction." Paragraph (2)(a) was also amended by s. 1, ch. 2009-45, and that version reads:

(2)(a) Unless the applicant has commenced construction, if the project provides for construction, unless the applicant has incurred an enforceable capital expenditure commitment for a project, if the project does not provide for construction, or unless subject to paragraph (b), a certificate of need shall terminate 3 years after the date of issuance. The agency shall monitor the progress of the holder of the certificate of need in meeting the timetable for project development specified in the application, and may revoke the certificate of need, if the holder of the certificate is not meeting such timetable and is not making a good-faith effort, as defined by rule, to meet it.
Note.—Former s. 381.710.

408.041 Certificate of need required; penalties.—It is unlawful for any person to undertake a project subject to review under ss. 408.031-408.045 without a valid certificate of need. Any person violating the provisions of this section is guilty of a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. Each day of continuing violation shall be considered a separate offense.

History.—s. 28, ch. 87-92; s. 62, ch. 91-224; s. 15, ch. 92-33; s. 14, ch. 95-144.
Note.—Former s. 381.711.

408.042 Limitation on transfer.—The holder of a certificate of need shall not charge a price for the transfer of the certificate of need to another person that exceeds the total amount of the actual costs incurred by the holder in obtaining the certificate of need. Such actual costs must be documented by an affidavit executed by the transferor under oath. A holder who violates this section is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082, or by a fine not exceeding $10,000, or both.

History.—s. 29, ch. 87-92; s. 15, ch. 92-33; s. 7, ch. 97-270.
Note.—Former s. 381.712.

408.043 Special provisions.—

(1) OSTEOPATHIC ACUTE CARE HOSPITALS.—When an application is made for a certificate of need to construct or to expand an osteopathic acute care hospital, the need for such hospital shall be determined on the basis of the need for and availability of osteopathic services and osteopathic acute care hospitals in the district. When a prior certificate of need to establish an osteopathic acute care hospital has been issued in a district, and the facility is no longer used for that purpose, the agency may continue to count such facility and beds as an existing osteopathic facility in any subsequent application for construction of an osteopathic acute care hospital.

(2) HOSPICES.—When an application is made for a certificate of need to establish or to expand a hospice, the need for such hospice shall be determined on the basis of the need for and availability of hospice services in the community. The formula on which the certificate of need is based shall discourage regional monopolies and promote competition. The inpatient hospice care component of a hospice which is a freestanding facility, or a part of a facility, which is primarily engaged in providing inpatient care and related services and is not licensed as a health care facility shall also be required to obtain a certificate of need. Provision of hospice care by any current provider of health care is a significant change in service and therefore requires a certificate of need for such services.

(3) RURAL HEALTH NETWORKS.—Preference shall be given in the award of a certificate of need to members of certified rural health networks, as provided for in s. 381.0406, subject to the following conditions:

(a) Need must be shown pursuant to s. 408.035.

(b) The proposed project must:

1. Strengthen health care services in rural areas through partnerships between rural care providers; or

2. Increase access to inpatient health care services for Medicaid recipients or other low-income persons who live in rural areas.

(c) No preference shall be given under this section for the establishment of skilled nursing facility services by a hospital.

(4) PRIVATE ACCREDITATION NOT REQUIRED.—Accreditation by any private organization may not be a requirement for the issuance or maintenance of a certificate of need under ss. 408.031-408.045.

History.—s. 30, ch. 87-92; s. 15, ch. 91-282; s. 15, ch. 92-33; s. 31, ch. 93-129; s. 8, ch. 97-270; s. 1, ch. 2003-161; s. 11, ch. 2004-383.
Note.—Former s. 381.713.

408.0435 Moratorium on nursing home certificates of need.—

(1) Notwithstanding the establishment of need as provided for in this chapter, a certificate of need for additional community nursing home beds may not be approved by the agency until Medicaid managed care is implemented statewide pursuant to ss. 409.961-409.985 or October 1, 2016, whichever is earlier.

(2) The Legislature finds that the continued growth in the Medicaid budget for nursing home care has constrained the ability of the state to meet the needs of its elderly residents through the use of less restrictive and less institutional methods of long-term care. It is therefore the intent of the Legislature to limit the increase in Medicaid nursing home expenditures in order to provide funds to invest in long-term care that is community-based and provides supportive services in a manner that is both more cost-effective and more in keeping with the wishes of the elderly residents of this state.

(3) This moratorium on certificates of need shall not apply to sheltered nursing home beds in a continuing care retirement community certified by the former Department of Insurance or by the Office of Insurance Regulation pursuant to chapter 651.

(4)

(a) The moratorium on certificates of need does not apply and a certificate of need for additional community nursing home beds may be approved for a county that meets the following circumstances:

1. The county has no community nursing home beds; and
2. The lack of community nursing home beds occurs because all nursing home beds in the county that were licensed on July 1, 2001, have subsequently closed.

(b) The certificate-of-need review for such circumstances shall be subject to the comparative review process consistent with the provisions of s. 408.039, and the number of beds may not exceed the number of beds lost by the county after July 1, 2001.

This subsection shall be repealed upon the expiration of the moratorium established in subsection (1).

(5) The moratorium on certificates of need does not apply for the addition of nursing home beds licensed under chapter 400 to a nursing home located in a county having up to 50,000 residents, in a number not exceeding 10 total beds or 10 percent of the number of beds licensed in the facility being expanded, whichever is greater. In addition to any other documentation required by the agency, a request submitted under this subsection must:

(a) Certify that the facility has not had any class I or class II deficiencies within the 30 months preceding the request for addition.

(b) Certify that the prior 12-month average occupancy rate for the nursing home beds at the facility meets or exceeds 94 percent and the facility had not had any class I or class II deficiencies since its initial licensure.

(c) For a facility that has been licensed for less than 24 months, certify that the prior 6-month average occupancy rate for the nursing home beds at the facility meets or exceeds 94 percent and that the facility has not had any class I or class II deficiencies since its initial licensure.

This subsection shall be repealed upon the expiration of the moratorium established in subsection (1).

(6) The moratorium on certificates of need does not apply for the addition of nursing home beds licensed under chapter 400 in a number not exceeding 10 total beds or 10 percent of the number of beds licensed in the facility being expanded, whichever is greater, if the facility meets the requirements of paragraph (a).

(a) In addition to any other documentation required by the agency, a request for the addition of beds under this subsection must certify that:

1. The facility has not had any class I or class II deficiencies within the 30 months preceding the request for addition;
2. The prior 12-month average occupancy rate for the nursing home beds at the facility meets or exceeds 96 percent;
3. The occupancy rate for nursing home beds in the subdistrict is 94 percent or greater; and
4. Any beds authorized for the facility under this subsection before the date of the current request for additional beds have been licensed and operational for at least 12 months.

(b) A nursing home may request additional beds under this subsection as an exemption from the provisions of s. 408.036(1). The timeframes and monitoring process specified in s. 408.040(2)(a)-(c) apply to any exemption issued under this subsection.

(c) The agency shall count beds authorized under this subsection as approved beds in the published inventory of nursing home beds until the beds are licensed.

This subsection shall be repealed upon the expiration of the moratorium established in subsection (1).

History.—s. 52, ch. 2001-45; s. 1693, ch. 2003-261; s. 12, ch. 2004-298; s. 14, ch. 2004-383; s. 1, ch. 2006-161; s. 4, ch. 2011-135.
Note.—Former s. 651.1185.

408.044 Injunction.—Notwithstanding the existence or pursuit of any other remedy, the agency may maintain an action in the name of the state for injunction or other process against any person to restrain or prevent the pursuit of a project subject to review under ss. 408.031-408.045, in the absence of a valid certificate of need.

History.—s. 31, ch. 87-92; s. 15, ch. 92-33; s. 15, ch. 95-144; s. 12, ch. 2000-256; s. 13, ch. 2000-318.
Note.—Former s. 381.714.

408.045 Certificate of need; competitive sealed proposals.—

(1) The application, review, and issuance procedures for a certificate of need for an intermediate care facility for the developmentally disabled may be made by the agency by competitive sealed proposals.

(2) The agency shall make a decision regarding the issuance of the certificate of need in accordance with the provisions of s. 287.057(16), rules adopted by the agency relating to intermediate care facilities for the developmentally disabled, and the criteria in s. 408.035, as further defined by rule.

(3) Notification of the decision shall be issued to all applicants not later than 28 calendar days after the date responses to a request for proposal are due.

(4) The procedures provided for under this section are exempt from the batching cycle requirements and the public hearing requirement of s. 408.039.

(5) The agency may use the competitive sealed proposal procedure for determining a certificate of need for other types of health care facilities and services if the agency identifies an unmet health care need and when funding in whole or in part for such health care facilities or services is authorized by the Legislature.

History.—s. 3, ch. 83-244; s. 42, ch. 85-81; s. 32, ch. 87-92; s. 3, ch. 89-308; s. 30, ch. 90-268; ss. 15, 18, ch. 92-33; s. 16, ch. 95-144; s. 13, ch. 2000-256; s. 14, ch. 2000-318; s. 67, ch. 2002-1; s. 37, ch. 2002-207; s. 33, ch. 2010-151.
Note.—Former s. 381.4961; s. 381.715.

408.0455 Rules; pending proceedings.—The rules of the agency in effect on June 30, 2004, shall remain in effect and shall be enforceable by the agency with respect to ss. 408.031-408.045 until such rules are repealed or amended by the agency.

History.—s. 38, ch. 87-92; s. 19, ch. 92-33; s. 74, ch. 92-289; s. 19, ch. 97-79; s. 4, ch. 97-98; s. 9, ch. 97-270; s. 12, ch. 2004-383.
Note.—Former s. 381.7155.