



SPONSOR: Rep. Dorsey Walker & Sen. Hoffner
Reps. Collins, K. Johnson, Parker Selby, Spiegelman;
Sens. Gay, Huxtable, Pettyjohn, Richardson

HOUSE OF REPRESENTATIVES
152nd GENERAL ASSEMBLY

HOUSE BILL NO. 394

AN ACT TO AMEND TITLE 16 OF THE DELAWARE CODE RELATING TO HEALTH PLANNING AND
RESOURCES MANAGEMENT.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

1 Section 1. Amend § 9301, Title 16 of the Delaware Code by making deletions as shown by strike through and
2 insertions as shown by underline as follows:

3 § 9301. Purpose.

4 ~~It is the~~ The purpose of this chapter ~~is~~ is to assure ~~that there is~~ continuing public scrutiny of certain health-care
5 developments which could negatively affect the quality of health care or threaten the ability of a health-care ~~facilities~~
6 facility to provide services to the medically indigent. This public scrutiny is to ~~be focused~~ focus on balancing concerns for
7 cost, ~~access and quality~~ access, and quality, while prioritizing value-based services over cost-driven outcomes.

8 Section 2. Amend § 9302, Title 16 of the Delaware Code by making deletions as shown by strike through and
9 insertions as shown by underline as follows and by redesignating accordingly:

10 § 9302. Definitions.

11 ~~The following words, terms and phrases, when used in this chapter, shall have the meanings ascribed to them in~~
12 ~~this section, except where the context indicates a different meaning~~ As used in this chapter:

13 (1) “Advisory Board” shall mean means the Delaware Health Resources Board ~~established pursuant to § 9303~~
14 ~~of this title.~~ Advisory Board established under this chapter.

15 (2) “Bureau” shall mean the Bureau of Health Planning and Resources Management within the Department of
16 ~~Health and Social Services.~~ [Repealed].

17 (3) “Application” means the formal, written request for a certificate of need.

18 (4) “Applicant” means the person who submits an application under this chapter.

19 (3) ~~(5) “Certificate of Public Review” shall mean need” means~~ the written approval of an application to
20 undertake an activity subject to review ~~as described in~~ under § 9304 of this title.

21 (4) “Commission” means the Delaware Health Care Commission.

22 (5) “DHIN” means the Delaware Health Information Network.

(6) "Department" means the Department of Health and Social Services.

(7) "Executive Director" means the Executive Director of the Delaware Health Care Commission.

(8) "Freestanding acute inpatient rehabilitation hospital" means a facility that satisfies, or is expected by the person who will construct, develop, or establish the facility to satisfy, the requirements of 42 C.F.R. § 412.23(b); if the facility is not paid under the prospective payment system specified in 42 C.F.R. § 412.1(a)(3) within 24 months after accepting its first patient, the facility is not a freestanding acute inpatient rehabilitation hospital under this paragraph.

(9) "Freestanding birthing center" means a facility licensed as a freestanding birthing center as defined in § 122 of this title.

(10) "Freestanding emergency department" means a facility licensed as a freestanding emergency department as defined in § 122 of this title.

(11) "Freestanding surgical center" means a facility licensed as a freestanding surgical center as defined in § 122 of this title and in which the expected duration of services would not exceed 23 hours 59 minutes following an admission.

(4) (12)a. "Health-care facility" ~~shall include~~ means any of the following:

1. ~~A hospital, nursing home long-term care facility,~~ freestanding birthing center, freestanding surgical center, freestanding acute inpatient rehabilitation hospital, ~~and or~~ freestanding emergency center, ~~whether or not department, regardless of being any of the following:~~

~~A. licensed~~ Licensed or required to be licensed by ~~the State,~~ this State.

~~B. whether operated~~ Operated for profit or ~~nonprofit~~ nonprofit.

~~C. and whether privately~~ Privately owned or operated or owned or operated by a unit of State or local government.

2. ~~The term also includes continual care communities and any other nontraditional, long-term care facilities identified by~~ A continual care community or another nontraditional, long-term care facility that the Department of Health and Social Services or the Delaware Health Care Commission identifies.

~~b. The term does not include~~ "Health-care facility" does not mean any of the following:

1. ~~A Christian Science sanatoriums~~ sanatorium operated or listed and certified by the First Church of Christ Christ Scientist, Boston, Massachusetts.

2. ~~The term shall not include any~~ A physician's office, whether an individual or group practice, any practice; an independent clinical laboratory or any laboratory; or a radiology laboratory.

3. ~~The term shall also not include the office of any other~~ An office of another licensed health-care provider, ~~including, but not limited to,~~ including a physical therapist, dentist, physician assistant, podiatrist, chiropractor, an independently practicing nurse or nurse practitioner, optometrist, ~~pharmacist~~ pharmacist, or psychologist.

4. ~~The term also shall not include any~~ A dispensary or first aid station located within a business or industrial establishment maintained solely for the use of the business's or establishment's employees, ~~provided that the facility~~ if the dispensary or first aid station does not contain inpatient beds, beds.

5. ~~nor shall it apply to any~~ A first aid station or dispensary or infirmary offering non-acute services exclusively for use by students and employees of a school or university or by inmates and employees of a prison, ~~provided that if the services delivered therein~~ are not the substantial equivalent of hospital services in the same area or community. ~~Further:~~

a. ~~"Freestanding acute inpatient rehabilitation hospital"~~ shall mean a facility that satisfies, or is expected by the person who will construct, develop or establish the facility to satisfy, the requirements of 42 C.F.R. § 412.23(b); ~~provided that, if such facility is not paid under the prospective payment system specified in 42 C.F.R. § 412.1(a)(3) within 24 months after accepting its first patient, then it shall not be considered a freestanding acute inpatient rehabilitation hospital under this section.~~

b. ~~"Freestanding birthing center"~~ shall mean any facility licensed as such pursuant to Chapter 1 of this title and more particularly in the State Board of Health Regulations.

c. ~~"Freestanding emergency center"~~ shall mean any facility licensed as such pursuant to Chapter 1 of this title and more particularly § 52 of the State Board of Health Regulations.

d. ~~"Freestanding surgical center"~~ shall mean any facility licensed as such pursuant to Chapter 1 of this title and more particularly in the State Board of Health Regulations.

e. ~~"Hospital"~~ shall mean any nonfederal facility licensed as such pursuant to Chapter 10 of this title and more particularly § 50 of the State Board of Health Regulations.

f. ~~"Nursing home"~~ shall mean any nonfederal facility licensed as such pursuant to Chapter 11 of this title and more particularly § 57 (Skilled care) and § 58 (Intermediate care) of the State Board of Health Regulations.

(5) (13) "Health-care resources" means materials, personnel, facilities, funds, or other resources that can be used for providing health-care services.

~~(14) “Health services” shall mean clinically related (i.e., diagnostic, curative or rehabilitative) “Health-care services” means services provided in or through health-care facilities. a health-care facility and that are clinically related, such as diagnostic, curative, or rehabilitative services.~~

~~(15) “Hospital” means a nonfederal facility licensed as a hospital as defined in §1001 of this title.~~

~~(16)a. “Long-term care facility” means a nonfederal facility that is licensed as a long-term care facility is defined in § 1102 of this title and is a residential facility that provides shelter and food to more than 1 individual who meets all of the following:~~

~~1. Because of the individual’s physical or mental condition, requires a level of care and services suitable to the individual’s needs to contribute to the individual’s health, comfort, or welfare.~~

~~2. Is not related within the second degree of consanguinity to the facility’s controlling person.~~

~~b. “Long-term care facility” includes a nursing facility and an intermediate care facility for persons with intellectual disabilities, as each of those terms is defined in § 1102 of this title.~~

~~(6) (17) “Major medical equipment” shall mean a single unit of medical equipment or a single system of components with related functions which is used for the diagnosis or treatment of patients and which:~~

~~a. Entails a capital expenditure as set forth in this chapter which exceeds \$5,800,000 or some greater amount which has been designated by the Board following an annual adjustment for inflation using an annual inflation index determined by the United States Department of Labor, Bureau of Labor Statistics;~~

~~b. Represents medical technology which is not yet available in Delaware; or~~

~~c. Represents medical technology which has been designated by the Board as being subject to review.~~

~~The Board may exempt from review a capital expenditure used to acquire major medical equipment which represents medical technology which is not yet available in Delaware. A notice of intent filed pursuant to § 9305 of this title along with any other information deemed necessary by the Board shall provide the basis for exempting such a capital expenditure from review. [Repealed.]~~

~~(7) (18) “Person” shall mean an individual, a trust or estate, a partnership, a corporation (including associations, joint stock companies and insurance companies), a state or political subdivision or instrumentality (including a municipal corporation) of a state. “Person” means as defined in § 302 of Title 1, and includes a trust or estate; an insurance company; a state; and a political subdivision or instrumentality of a state, including a municipal corporation.~~

~~(19) “Proposed project” means the enterprise for which an application for a certificate of need is filed.~~

~~(20) “Review” means the assessment of an application for a certificate of need.~~

Section 3. Amend § 9303, Title 16 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 9303. Delaware Health Resources Advisory Board.

(a) ~~There is hereby established a Delaware Health Resources~~ The Advisory Board ~~to foster~~ is established for the purpose of advising the Executive Director regarding both of the following:

(1) ~~the~~ The cost-effective and efficient use of health-care ~~resources~~ resources.

(2) ~~and the~~ The availability of and access to high quality and appropriate health-care services.

(b) Advisory Board membership; terms; quorum; compensation; staffing. ~~The Board shall consist of a Chair, a Vice Chair and 13 other members, all of which shall be appointed by the Governor. Appointments shall be for 3-year terms, provided that the terms of newly appointed members will be staggered so that no more than 5 appointments shall expire annually. The Governor may appoint members for terms of less than 3 years to ensure that the board members' terms expire on a staggered basis. The membership shall be representative of all counties in the State. In addition to the Chair and the Vice Chair, the membership shall consist of 1 representative of the Delaware Health Care Commission; 1 representative from the Department of Health and Social Services recommended by the Secretary of the Department of Health and Social Services; 1 representative of labor; 1 representative of the health insurance industry; 1 representative with knowledge and professional experience in health care administration; 1 representative licensed to practice medicine in Delaware; 1 representative with knowledge and professional experience in long-term care administration; 1 representative of a provider group other than hospitals, nursing homes or physicians; 1 representative involved in purchasing health care coverage on behalf of State employees; 1 other representative involved in purchasing health care coverage for employers with more than 200 employees; and 4 representatives of the public at large. Public members may include but not be limited to representative from business, educational and nonprofit organizations. The Chair shall be an at-large position and shall be appointed by and serve at the pleasure of the Governor. The Governor shall designate a Vice Chair from among the members of the Board who shall serve in this capacity at the pleasure of the Governor. The Delaware Healthcare Association, the Medical Society of Delaware, the Delaware Health Care Facilities Association, the Delaware State Chamber of Commerce, and other interested organizations may submit nonbinding recommendations to aid the Governor in making appointments to the Board. Any vacancy shall be filled by the Governor for the balance of the unexpired term. A quorum shall consist of at least 50% of the membership. Members of the Board shall serve without compensation, except that they may be reimbursed for reasonable and necessary expenses incident to their duties, to the extent that funds are available and the expenditures are in accordance with state laws.~~

(1) The Advisory Board is composed of 10 members, as follows:

a. Seven voting members that the Governor appoints, as follows:

1. One member who represents labor.

2. One member who represents the health insurance industry.

3. One member who has professional experience in health-care economic and policy matters.

4. One member who is licensed to practice medicine in Delaware.

5. One member who has professional experience in long-term care administration.

6. One member who represents a provider group other than a hospital, long-term care facility, or physician.

7. One member who is involved in purchasing health-care coverage on behalf of State employees.

b. Three ex officio, nonvoting members, each of whom may select a designee from the organization that the member represents to serve in the member's stead and at the member's pleasure:

1. The Executive Director of the Delaware Health Care Commission.

2. The Director of the Office of Health Facilities Licensing and Certification.

3. The Director of the Office of Healthcare Provider Resources, Division of Public Health.

(2) Membership must represent all 3 counties in this State.

(3) Each voting member is appointed for a term of 3 years. The Governor may appoint a member for a term of less than 3 years to ensure that members' terms expire on a staggered basis. The Governor shall fill a vacancy by appointing a member for the balance of the unexpired term.

(4) A majority of voting members must be present at an Advisory Board meeting in order to have a quorum and conduct official business. None of the following are counted for the purposes of establishing quorum:

a. A vacancy on the Advisory Board.

b. A member's recusal from voting on a matter.

c. An ex officio, nonvoting member.

(5) The Advisory Board shall annually elect a chair and vice chair from among its members. An ex officio member may not serve as chair or vice chair.

(6) The Delaware Healthcare Association, Medical Society of Delaware, Delaware Health Care Facilities Association, Delaware State Chamber of Commerce, and another interested organization may provide a nonbinding recommendation that the Governor may use in considering an appointment to the Advisory Board.

(7) A member receives no compensation but may be reimbursed for the member's actual and necessary expenses incurred in the performance of the member's official duties, to the extent that funds are available and the expenditure is in accordance with state law.

~~(c) The Board is an independent public instrumentality. For administrative and budgetary purposes only, the Board shall be placed within the Department of Health and Social Services, Office of the Secretary. The Delaware Health Resources Board shall function in cooperation with the Delaware Health Care Commission, as well as other state health policy activities. Staff support for the Board shall be provided by the Delaware Health Care Commission and the Office of the Secretary, Department of Health and Social Services. The Department, through the Office of the Secretary, provides the Advisory Board with administrative, budgetary, and staff support. The Advisory Board functions in cooperation with the Department, Commission, and other state health policy activities.~~

~~(d) The duties and responsibilities of the Board shall include, but not be limited to, Advisory Board's duties and responsibilities include all of the following:~~

~~(1) Develop a Health Resources Management Plan which shall assess the supply of health care resources, particularly facilities and medical technologies, and the need for such resources. Essential aspects of the plan shall include a statement of principles to guide the allocation of resources, as well as rules and regulations which shall be formulated for use in reviewing Certificate of Public Review applications. Any revision of the Health Resources Management Plan shall be done in accordance with the provisions of the Administrative Procedures Act (Chapter 101 of Title 29). The Board shall also be required to conduct a public hearing. Also, prior to adoption, the plan or revision of the plan shall be submitted to the Delaware Health Care Commission for review and approval. Upon receiving written approval from the Commission, the plan or revision shall be submitted to the Secretary, Department of Health and Social Services. The plan or revision shall become effective upon the written approval of the Secretary;~~
[Repealed.]

~~(2) Review Certificate of Public Review applications filed pursuant to this chapter and make decisions on same. Decisions and advise the Executive Director whether to approve or deny an application for a certificate of need filed under this chapter. The Advisory Board must base its findings and advice on the criteria under § 9306 of this title and shall reflect the importance of assuring that health-care developments do not negatively affect the quality of health care or threaten the ability of a health-care facilities facility to provide services to the medically indigent. Decisions can be conditional but the conditions A finding to approve an application may be conditional, but each condition must be related to the specific project in question; to which the application relates. The Executive Director shall issue the final decision whether to approve an application, under § 9305(c)(7) of this chapter.~~

(3) ~~Gather and analyze data and information needed to carry out its responsibilities. Identify the kinds of data which are not available so that efforts can be made to assure that legitimate data needs can be met in the future;~~
[Repealed.]

(4) Address a specific health-care issues as requested by issue that the Governor or the General Assembly;
Assembly may request.

(5) Adopt bylaws as necessary for conducting its affairs. ~~Board members shall~~ A member must comply with the provisions of Chapter 58 of Title 29 (State Ethics Code) and the ~~Board shall operate in accordance with Chapter 100 of Title 29 (Freedom of Information Act); and Act).~~

(6) Coordinate activities with the ~~Delaware Health Care Commission, the Department of Health and Social Services and other groups as~~ the Department, or another group as appropriate or that the Department Secretary requests.

(7) Provide advice to the Department regarding the production of the biennial state-wide health-care facility utilization study under § 9312 of this title.

(c) The Governor may ~~at any time, after notice and hearing, remove any board~~ remove an Advisory Board member for gross inefficiency, neglect of duty, malfeasance, ~~misfeasance~~ misfeasance, or nonfeasance in office. A member ~~shall be~~ is deemed in neglect of duty if ~~they are~~ the member is absent from 3 consecutive ~~board~~ Advisory Board meetings without good cause or if ~~they attend~~ the member attends less than 50% of ~~board~~ regular Advisory Board meetings in a calendar year. The Governor may consider the member to have resigned and may accept the member's resignation.

Section 4. Amend § 9304, Title 16 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 9304. ~~Activities~~ Certificate of need required; activity subject to review ~~[Effective Dec. 31, 2020].~~

(a) ~~Any~~ A person must obtain a ~~Certificate of Public Review~~ certificate of need prior to undertaking any of the following activities:

(1) The construction, development or other establishment of a health-care ~~facility~~ facility, or the ~~for-profit~~ acquisition of a nonprofit health-care ~~facility;~~ facility.

(2) ~~Any~~ a. An expenditure by or on behalf of a health-care facility in excess of ~~\$5.8~~ \$8 million, or some greater amount ~~which has been designated by the Board~~ designates following an annual adjustment for inflation using an annual inflation index determined by the United States Department of Labor, Bureau of Labor Statistics, ~~is a capital expenditure.~~ for the expansion, modification, development, or alteration of a health-care facility.

b. A capital expenditure for purposes of constructing, ~~developing~~ developing, or otherwise establishing a medical office building ~~shall not be~~ is not subject to review under this chapter.

c. When a person makes an acquisition by or on behalf of a health-care facility under lease or comparable arrangement, or through donation which would have required review if the acquisition had been by purchase, ~~such~~ the acquisition shall be deemed is a capital expenditure subject to review.

d. The ~~Board~~ Executive Director may exempt from review ~~a capital expenditures when determined to be expenditure when the Executive Director determines the expenditure is~~ necessary for maintaining the physical structure of a facility and not related to direct patient care. A notice of intent filed ~~pursuant to~~ under § 9305 of this title, along with any other information ~~deemed necessary by the Board, shall provide~~ the Executive Director deems is necessary, provides the basis for exempting ~~such capital expenditures from review; a capital expenditure from review.~~

(3) A change in bed capacity of a health-care facility which increases the total number of ~~beds~~ beds, distributes beds among various categories, or relocates ~~such~~ the beds from 1 physical facility or site to ~~another~~ another, by more than 10 beds or more than ~~10 percent~~ 10% of total licensed bed capacity, whichever is less, over a 2-year ~~period; period.~~

~~(4) The acquisition of major medical equipment, whether or not by a health care facility and whether or not the acquisition is through a capital expenditure, an operating expense or a donation. The replacement of major medical equipment with similar equipment shall not be subject to review under this chapter. In the case of major medical equipment acquired by an entity outside of Delaware, the use of that major medical equipment within Delaware, whether or not on a mobile basis, is subject to review under this chapter. Major medical equipment which is acquired for use in a freestanding acute inpatient rehabilitation hospital, as defined in § 9302(4) of this title, a dispensary or first aid station located within a business or industrial establishment maintained solely for the use of employees or in a first aid station, dispensary or infirmary offering services exclusively for use by students and employees of a school or university or by inmates and employees of a prison is not subject to review. [Repealed.]~~

~~(5) [Expired].~~

~~(b) [Expired].~~

Section 5. Amend § 9305, Title 16 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 9305. ~~Procedures for review.~~ Regulations; forms; procedures for review; notice of intent; reconsideration; appeal; fees.

(a) The Department may promulgate rules and regulations to implement this section.

(b) The Department shall develop a form or multiple forms for an application under this chapter. An application form must include each review consideration under § 9306 of this title. The Department shall make each form of application available on the Department's website.

(c) ~~Reviews~~ A review under this chapter shall must be conducted ~~in accordance with~~ under the following procedures:

(1) ~~Notices~~ a. Notice of intent. At least 30 days but not more than 180 days ~~prior to~~ before submitting an application for review under this chapter, ~~applicants~~ an applicant shall submit to the ~~Bureau~~ Department a notice of intent in ~~such form as may be determined by the Board~~ a form that the Department determines to cover the scope and nature of the proposed project. An application may be submitted less than 30 days from submitting the notice of intent only with the Executive Director's written ~~approval of the Board.~~ approval.

b. A notice of intent expires and is rendered invalid if ~~no subsequent~~ an application for review is not submitted to the ~~Board~~ Executive Director within 180 days following the date on which the notice of intent is submitted.

c. An applicant shall publish an advertisement in a newspaper of general circulation in the defined service area which briefly describes the proposed project, the location of the services, and a statement that a notice of intent to apply for a certificate of need will be filed with the Department.

d. An applicant shall provide a copy of the published advertisement under paragraph (c)(1)c. of this section with the applicant's notice of intent.

e. The Department shall publish each notice of intent on the Department's website.

(2) ~~Applications for review. Application forms will be developed by the Board and may vary according to the nature of the application.~~ Application for certificate of need. An applicant must submit a complete application with all documentation that the Department requests.

(3) ~~Deadlines and time limitations.~~ Deadline and time limitation.

a. Upon receipt of an application under this chapter, the ~~Bureau shall have~~ Department has a maximum of 15 business days to notify the applicant as to whether the application is considered complete. ~~If complete, written~~

notification in accordance with paragraph (4) of this section will be provided. If incomplete, the applicant will be notified in writing of such determination and will be advised of what additional information is required to make the application complete. When the additional information is received, the Bureau again has a maximum of 15 business days to determine whether the application is complete. If complete, the Department shall provide the applicant with written notification under paragraph (c)(4) of this section. The Department shall notify the applicant in writing if the Department determines that the application is incomplete. The same steps shall must be taken as with the initial submission each time that additional information is required.

b. Except as provided below, in paragraph (c)(3)c. of this section, the Department shall complete a review of an application shall take no longer than 90 days from the date of notification as covered under paragraph (c)(4) of this section. If a public hearing is requested under paragraph (6) of this section, the maximum review period will be extended to 120 days from the date of notification. Within 30 days from the date of notification (60 days if a public hearing is requested), notification, the Board Department may extend the maximum review period up to 180 days from the date of notification. Such extensions shall be invoked The Department may grant an extension only as necessary to allow the development of appropriate review criteria Department staff to conduct the necessary research under paragraph (c)(5) or other guidance when these are if research or guidance is lacking or to facilitate the simultaneous review of similar applications. The maximum review period can also be extended as mutually agreed to in writing by the Board and the applicant. the Department and applicant mutually agree, in writing.

c. Abbreviated application. In the case of a project required to remedy an emergency situation which threatens the safety of patients or the ability of ~~the health~~ a health-care facility to remain in operation, an abbreviated application shall must be submitted in ~~such~~ the format as the ~~Board~~ Department prescribes. As quickly as possible, but within 72 hours after receipt of the abbreviated application, the ~~Board~~ Executive Director shall ~~render a decision as to~~ determine, without input from the Advisory Board, whether ~~or not~~ the project shall be is treated as an emergency and whether ~~or not~~ the abbreviated application shall be is approved. ~~The Chair or Vice Chair of the Board shall be authorized to render such decision and shall have discretion as to the decision making process.~~

(4) ~~Agency~~ Executive Director review; notification.

a. Within 5 working days of determining that an application under this chapter is complete, the ~~Bureau~~ Department shall provide written notification of the beginning of a review. ~~Such notification shall be sent directly to all health care facilities in the State and to others who request direct notification. The Department shall directly~~

313 notify each health-care facility in this State of the review. The Department shall also directly notify another
314 person, if any, who requests notification.

315 b. A notice shall also appear in a newspaper of general circulation which shall serve as written
316 notification to the general public. The date of notification is the date on which such notice appears in the
317 newspaper. The notification shall identify the applicant, indicate the nature of the application, specify the period
318 during which a public hearing in the course of the review as covered in paragraph (6) of this section may be
319 requested, and indicate the manner in which notice will be provided of the time and place of any hearing so
320 requested. The Department shall publish on the Department's website a notice of the review.

321 (5) Findings. Department staff analysis, findings, and report; public comment.

322 a. Department staff shall do all of the following:

323 1. Use the information provided in the application to prepare an analysis of the proposed project,
324 including information on the proposed project and a description of the applicant's plan.

325 2. Analyze the proposed project under the review considerations under § 9306 of this title.

326 3. Complete a report of staff's analysis no later than 45 days after the Department provides written
327 notification of the beginning of a review under paragraph (c)(4)a. of this section.

328 b. Upon completion of a review under this chapter, and within the time frames outlined in paragraph (3)
329 of this section, the Bureau shall notify in writing the applicant and anyone else upon request as to the Board's
330 decision, including the basis on which the decision was made. Decisions can be conditional, but the conditions
331 must be related to the specific project in question. Upon completion of the staff report under this section, the
332 Department shall provide notification to the applicant that the staff report is complete and an electronic copy of the
333 report. The Department shall also provide notification and an electronic copy of the report to another person, if
334 any, who requests direct notification. The Department shall publish the staff report on the Department's website,
335 along with instructions, including the deadline, for the public to provide written public comment on the report.

336 c. Written public comment may be provided on each review for 30 calendar days from the date the staff
337 report is published on the Department's website.

338 (6) Advisory Board meeting and findings. Public hearing in the course of review. Within 10 days after the
339 date of notification as described in paragraph (4) of this section, a public hearing in the course of review may be
340 requested in writing by any person. The Board shall provide for a public hearing if requested and shall provide
341 notification of the time and place for such hearing in a newspaper of general circulation. The public hearing shall be

held not less than 14 days after such notice appears in the newspaper. Fees shall not be imposed for such hearings. An opportunity must be provided for any person to present testimony.

a. Advisory Board meeting. No later than 30 days after the Department publishes the Department staff report on the Department's website, the Advisory Board shall hold an initial meeting to receive an overview from the applicant of the proposed project, an overview from Department staff of the staff's analysis and report, and public comment.

1. The Department shall provide electronically the Advisory Board with written public comment received prior to the Advisory Board's initial meeting. Only the Executive Director may consider written public comment submitted after the Advisory Board's initial meeting.

2. The Advisory Board may hold 1 additional meeting after the initial meeting to review an application. The additional meeting must be held within the 30-day written public comment period under paragraph (c)(5)c. of this section. The meetings may be scheduled consecutively.

3. At an Advisory Board meeting, the Advisory Board shall discuss the application at issue and the related staff report. At the Advisory Board's request, the applicant may provide clarification on a matter relating to the application, proposed project, or staff report.

b. Determination. The Advisory Board shall vote at the final meeting held on the application whether to advise the Executive Director to approve the application. The Advisory Board shall provide the Executive Director with the result of the vote within 7 calendar days of the vote. The Department shall publish on the Department's website the result of the Advisory Board's vote.

~~(7) Administrative reconsideration Procedure for Board.~~ Executive Director's decision; administrative reconsideration.

a. The Executive Director shall make the decision whether to approve an application for a proposed project, no later than 30 days after the closing of the written public comment period under paragraph (c)(5)c. of this section. In making a decision, the Executive Director shall consider all of the following:

1. The Advisory Board's findings under paragraph (c)(6) of this section.

2. The Department staff's report under paragraph (c)(5) of this section.

3. All materials that the applicant submits.

4. Whether to make the decision conditional. Each condition must be related to the proposed project at issue.

b. The Department shall notify the applicant, and others who request to be notified, in writing of the Executive Director's decision and the reasoning for the decision. The Department shall publish the decision and reasoning on the Department's website.

c. Administrative reconsideration.

1. Any A person may, for a good cause shown, request in writing a public hearing for purposes of reconsideration of a Board to reconsider the Executive Director's decision rendered under paragraph (5) (c)(7) of this section. The Board Department may not impose fees for such a hearing a fee for a hearing under this paragraph. For purposes of this paragraph, a request for a public hearing shall be deemed by the Board to have shown good cause if it: A request for a public hearing under this paragraph is made with good cause shown if the person requesting the hearing meets either of the following criteria:

a. A. Does both of the following:

I. Presents newly discovered, significant, and relevant information that was not previously available or considered by the Board; and the Executive Director did not previously consider.

b. II. Demonstrates that there have been significant changes in factors or circumstances that the Executive Director relied upon by the Board in reaching its decision; or a decision.

e. B. Demonstrates that the Board has Executive Director materially failed to follow its the Department's adopted procedures in reaching its decision.

2. A person making a request for such a hearing under this paragraph (c)(7)c. must be received submit the request within 10 days of the Executive Director's decision. The hearing shall commence Department shall schedule a hearing to take place within 45 days of receiving the request.

3. Notice of such public hearing shall be sent, not less than 15 days prior to the date of the hearing, to the person requesting the hearing and to the applicant, and shall be sent to others upon request. The Executive Director shall provide notice for a public hearing under this paragraph (c)(7)c. not less than 15 days prior to the date of the hearing. The notice must be provided to the person requesting the hearing, the applicant for the proposed project, and others who requested to be noticed.

4. Following completion of the hearing, the Board Executive Director shall, within 45 days, issue its a written decision which shall set forth must include the findings of fact and conclusion of law upon which its the decision is based.

(8) Appeal Applicant. Judicial appeal.

a. Any of the following may be appealed to the Superior Court:

1. A decision of the ~~Board~~ Executive Director following review of an application pursuant to ~~under~~
paragraph (c)(5) of this ~~section~~, section.

2. ~~an~~ An administrative reconsideration pursuant to ~~under~~ paragraph (c)(7) of this ~~section~~, or section.

3. ~~the~~ The denial of a request for extension of a ~~Certificate of Public Review~~ pursuant to certificate of
need under § 9307 of this title, title.

~~b. may be appealed within 30 days to the Superior Court.~~ An appeal under this paragraph (c)(8) of this
section must be filed within 30 days of the occurrence of the decision being appealed.

~~c. Such appeal shall~~ An appeal under this paragraph must be on the record.

(9) Access by public. The Department shall provide the general public ~~shall be provided with~~ access to all
~~applications~~ each application reviewed under this chapter and to all other written materials pertinent to ~~any~~ a review of
an application.

(10)a. Filing fees. Within 5 working days of determining that an application under this chapter is complete,
the ~~Bureau~~ Department shall notify the applicant of ~~any~~ the filing fee ~~due~~. due, if any.

~~b. Filing fees shall~~ The filing fee for an application must be determined from the following table:

Capital Expenditure	Fee
Less than \$500,000	\$100
\$500,000 to \$999,999	\$750
\$1,000,000 to \$4,999,999	\$3,000
\$5,000,000 to \$9,999,999	\$7,500
\$10,000,000 and over	\$10,000

~~c. Filing fees shall be~~ The filing fee is due 30 days after the date of notification of the beginning of review as
~~covered under paragraph (4)~~ under paragraph (c)(4) of this section. This The Executive Director may extend the due date
~~may be extended up to 10 additional days at the discretion of the Bureau.~~ days.

d. Applications An application for which a filing fees ~~have~~ fee has not been paid ~~within this time frame shall be by~~
the due date or extended due date is considered to be withdrawn.

~~e. All filing fees shall~~ Each filing fee must be deposited in the General Fund.

Section 6. Amend § 9306, Title 16 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 9306. Review considerations.

In conducting ~~reviews~~ a review of an application under this chapter, the Advisory Board and Executive Director shall consider as ~~appropriate~~ at least all of the following:

(1) ~~The relationship of the proposal to the Health Resources Management Plan adopted pursuant to § 9303 of this title. Prior to adoption of a Health Resources Management Plan by the Board, the State health plan last in use by the Health Resources Management Council shall comprise such plan; [Repealed.]~~

(2) ~~The need of the population for the proposed project;~~ project. To determine the need, the applicant for the certificate shall provide, and the Advisory Board and Executive Director shall consider, all of the following:

a. A detailed narrative that supplies rationale for the proposed project and includes the defined service area of the project.

b. Facts demonstrating a clear public need for the proposed project, including demographic, incidence, prevalence, outcomes, and survival data of the population to be served by the project.

c. At the Advisory Board's or Executive Director's request, the applicant's calculation and supply of mathematical need calculations.

1. The applicant shall obtain population estimates and projections from the Delaware Population Consortium and the U.S. Census Bureau.

2. The Advisory Board and Executive Director shall use mathematical need calculations to ensure that the review is multi-faceted.

d. Supporting documents, such as articles, scientific studies, or reports, that corroborate statements made in the application to justify the need for the proposed project. The applicant must include a brief explanation of the relevance of each document provided under this paragraph.

e. Quantitative or qualitative supporting data, such as improvements to accessibility, availability, recent technology, advances in medical science, or morbidity or mortality data if the applicant anticipates that the proposed project will enhance the health status of the population to be served by the project.

(3) Information on alternatives, including both of the following:

a. The availability of less costly ~~and/or~~ or more effective alternatives to the ~~proposal~~ proposed project, including alternatives involving the use of resources located outside the ~~State~~; State.

b. The applicant's information about alternative providers of the proposed project, referencing the specific providers that currently offer the services included in the project and the impact of those providers. The applicant must include financial information showing whether the alternative providers are costly in the delivery of the services.

(4)a. The relationship of the ~~proposal~~ proposed project to the existing health-care delivery system; system and the predicted effect on the quality and access of health care in the defined service area.

b. The proposed project's relevance to access and continuity of care, chronic disease management, care coordination, use of telemedicine and health information technology, affiliation with the Delaware Health Information Network, and other strategies to facilitate Delaware's transition to value-based payment models to improve overall health outcomes.

1. An applicant should not propose a project that reflects or promotes incentives for overuse, medically unnecessary care, or low-value care.

2. A proposed project should support a managed coordinated approach to serve the health-care needs of the defined service area.

3. A proposed project that is intended to establish a new health-care facility must document that the applicant has done or will do each of the following:

A. Sign a participation agreement with DHIN.

B. Submit service records to the DHIN.

C. Access data and information from DHIN for coordination purposes.

c. The applicant's plan for care of a patient without private insurance coverage.

d. The applicant's plan for care of medically underserved populations within the defined service area.

e. The applicant's past and projected health-care services to Medicaid patients and the medically indigent, highlighting change in the access to services for Medicaid recipients and the medically indigent.

f. The applicant's plan for prevention activities such as early detection and the promotion of healthy lifestyles which are part of Delaware's statewide health-care reform efforts essential to an effective health-care system, including a number of opportunities to improve the health status of Delawareans.

(5) The immediate and long-term viability of the ~~proposal~~ proposed project in terms of the applicant's access to financial, ~~management~~ management, and other necessary ~~resources~~; resources.

a. The applicant must satisfactorily demonstrate the financial feasibility of the proposed project and included in the application a copy of study findings if a financial feasibility study was performed.

b. The applicant must include in the application proof of each funding or financing source of the proposed project, including applicable details such as the dollar amount of each, interest rate, term, monthly payment, pledge, or funds received to date, and letters of interest or approval from a lending institution.

(6) ~~The anticipated predicted effect of the proposal proposed project on the costs of and charges for health care; and care.~~ The applicant must satisfactorily show all of the following:

a. How the proposed project will affect the financial strength of the health-care system in the defined service area.

b. How the proposed project will improve cost-effectiveness of the health-care system in the defined service area.

c. How the proposed project will affect cost and charges to consumers for health-care services in the defined service area.

(7) ~~The anticipated effect of the proposal on the quality of health care.~~ [Repealed.]

(8) Supplemental information from the applicant showing the applicant's ability to support the proposed project and the applicant's commitment to appropriately balance consideration of access, cost, and quality of care issues, including both of the following:

a. The applicant's relevant certification and accreditation statuses, including those from Medicare, Medicaid, Joint Commission, or another accrediting organization.

b. A copy of each letter the applicant has received, if any, in support of the proposed project.

Section 7. Amend § 9307, Title 16 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 9307. Period of effectiveness of ~~Certificate of Public Review~~ certificate of need.

(a) ~~A Certificate of Public Review shall be valid for 1 year from the date such approval was granted.~~ A certificate of need is valid for 1 year from the date the certificate is approved.

(b) (1) ~~At least 30 days prior to the expiration of the Certificate of Public Review, the applicant~~ certificate of need, the holder of the certificate shall inform the Board Executive Director in writing of the project's status. The Board Executive Director shall determine if sufficient progress has been made for the Certificate of Public Review certificate of need to continue in effect. If sufficient progress has not been made, the applicant holder may request a 6-month extension in writing, to the Board, that a 6-month extension be granted Executive Director. The Board Executive Director shall either allow the certificate to expire or grant such the extension. A The Executive Director's decision by the Board to deny an extension may be appealed pursuant to under § 9305(8) of this title.

(2) The Department shall publish on its website each project status update, including extension requests and the Executive Director's decision of each request.

Section 8. Amend § 9308, Title 16 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 9308. Sanctions.

(a) ~~Any person undertaking an activity subject to review as described in § 9304 of this title, without first being issued a Certificate of Public Review for that activity, shall have its license or other authority to operate denied, revoked or restricted as deemed appropriate by the responsible licensing or authorizing agency of the State and an order in writing to such effect shall be issued by that licensing or authorizing agency.~~ The licensing or authorizing agency of the State that is responsible for a person who undertakes an activity that is subject to review under § 9304 of this title without first being issued a certificate of need shall deny, revoke, or restrict the person's license or other authority. The licensing or authority agency shall issue a written order establishing the denial, revocation, or restriction of the license or other authority.

(b) In addition to subsection (a) of this section, the ~~Board~~ Executive Director or ~~any~~ an adversely affected ~~health care~~ health-care facility may maintain a civil action in the Court of Chancery to restrain or prohibit ~~any~~ a person from undertaking an activity subject to review ~~as described in~~ under § 9304 of this title without first being issued a ~~Certificate of Public Review~~ certificate of need.

(c) A person who wilfully undertakes an activity subject to review ~~as described in~~ under § 9304 of this title and who has not received a ~~Certificate of Public Review~~ certificate of need for that activity shall must be fined not less than \$500 nor more than \$2,500 for each ~~offense and each~~ offense. Each day of a continuing violation after notice of violation ~~shall be considered~~ is a separate offense. The Superior Court ~~shall have~~ has jurisdiction over criminal violations under this subsection.

Section 9. Amend § 9309, Title 16 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 9309. Surrender, ~~revocation~~ revocation, and or transfer of ~~Certificate of Public Review~~ certificate of need.

(a) Surrender. ~~A Certificate of Public Review may be surrendered by the holder upon written notification to the Board and such surrender shall become effective immediately upon receipt of the Board.~~ The holder of a certificate of need may surrender the certificate upon written notification to the Executive Director. The surrender is effective immediately upon the Executive Director's receipt of the written notification.

(b) Revocation. ~~A Certificate of Public Review may be revoked by the Board in the case of misrepresentation in the Certificate of Public Review application, failure to comply with conditions established by the Board pursuant to §~~

9303(d)(2) of this title, failure to undertake the activity for which the Certificate of Public Review was granted in a timely manner or loss of license or other authority to operate.

(1) The Executive Director may revoke a certificate of need for any of the following reasons:

a. Misrepresentation in the application.

b. The failure of the holder of the certificate of need to comply with conditions established under § 9303(d)(2) of this title.

c. The failure of the holder of the certificate of need to undertake in a timely manner the activity for which the certificate was granted.

d. The loss of license or other authority to operate of the holder of the certificate of need.

(2) ~~Prior to revoking a Certificate of Public Review, the Board~~ certificate of need, the Executive Director shall provide written notice to the holder of the certificate stating ~~its~~ the Executive Director's intent to revoke the certificate and providing the holder at least 30 days to voluntarily surrender the certificate or to show good cause why the certificate should not be revoked.

(3) ~~No Certificate of Public Review shall be revoked by the Board~~ The Executive Director may not revoke a certificate of need without first providing the holder of the certificate an opportunity for a hearing.

(4) ~~The Board's Executive Director's decision to revoke a Certificate of Public Review~~ certificate of need may be appealed ~~pursuant to § 9305(8)~~ under § 9305(c)(8) of this title.

(c) ~~Transfer. No Certificate of Public Review issued under this chapter, and no rights or privileges arising therefrom, shall be subject to transfer or assignment, directly or indirectly, except upon order or decision of the Board specifically approving the same, issued pursuant to application supported by a finding from the evidence that the public to be served will not be adversely affected thereby.~~ A holder of a certificate of need may not transfer or assign, directly or indirectly, the certificate or the rights or privileges arising from the certificate, unless the Executive Director issues an order or decision specifically approving the transfer or assignment. The Executive Director's order or decision must be issued under a written request by the certificate holder supported by a finding from the evidence that the transfer or assignment will not adversely affect the public to be served by the transfer or assignment. The Department may establish a form for a transfer or assignment request.

Section 10. Amend § 9310, Title 16 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 9310. Immunity.

(a) ~~No A member, officer officer, or employee of the Board, the Bureau or health care facility shall be Advisory Board, Department, or a health-care facility is not subject to, and such persons shall be and is immune from, any a claim, suit, liability, damages or any other damages, or another recourse, civil or criminal, arising from any an act or proceeding, decision or determination undertaken or performed, or recommendations recommendation made while discharging any a duty or authority under this chapter, chapter.~~

(b)(1) ~~so long as such person~~ Subsection (a) of this section applies only if the member, officer, or employee acted in good faith, without malice, and within the scope of ~~such person's~~ member's, officer's, or employee's duty or authority under this chapter or ~~any other provisions~~ another provision of the Delaware law, federal law law, or regulations or duly adopted rules and regulations providing for the administration of this ~~chapter, chapter.~~

(2) ~~good faith being presumed until proven otherwise, with malice to be shown by the complainant. Good faith is presumed until proven otherwise, and the complainant has the burden to show that malice existed.~~

Section 11. Amend § 9311, Title 16 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 9311. Charity care.

(a) ~~Any person subject to a CPR review pursuant to~~ An applicant subject to review under this chapter shall do all of the following:

(1) ~~perform~~ Perform and accept within this State charity care to the extent ~~required by the Board that the Department requires to those individuals who meet~~ each individual who meets the criteria for rendering charity care ~~established by the Board, as the Department determines.~~

(2) ~~and shall continue~~ Continue to provide charity care in each fiscal year as ~~determined by the Board the~~ Department determines.

(b) ~~The authority to enforce charity care requirements shall rest with the Department of Health and Social Services. The Department shall enforce charity care requirements.~~

(c) The Department may promulgate rules and regulations for charity care.

(d) The Department shall publish each received charity care plan or report on the Department's website.

Section 12. Amend § 9312, Title 16 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 9312. ~~Charity care [Transferred]~~. Utilization statistics and statewide health-care facility utilization study.

(a)(1) An applicant subject to a review under this chapter shall report utilization statistics to the Department annually using a form that the Department establishes.

(2) Each health-care facility in this state shall provide utilization data to the Department, to assist the Department in completing the utilization study required under subsection (e) of this section.

(b) The Secretary of the Department may collect annual utilization reporting requirements.

(c) The Department may promulgate rules and regulations for collecting and reporting utilization statistics.

(d) The Department shall use reported utilization statistics in the production of a state-wide health-care facility utilization study.

(e) The Department shall conduct and produce a state-wide health-care facility utilization study biennially.

(1) The Department may use contract support to produce the study.

(2) The Advisory Board shall advise the Department on the production of the study.

(3) The study shall include assessments of each of the following in Delaware:

a. Current cost, availability, and utilization of acute hospital care.

b. Hospital emergency care.

c. Specialty hospital care.

d. Outpatient surgical care.

e. Primary care and clinic care.

f. Long-term care.

g. Assisted living care.

h. Rest residential home care.

i. Geographic areas and subpopulations that may be underserved or have reduced access to specific types of health-care services.

j. Unmet needs of persons at risk and vulnerable populations as the Department determines, with advice from the Advisory Board in determining the persons and populations.

k. Projection of future demand for health-care services and the impact that technology may have on the demand, capacity, or need for the services, and recommendations for the expansion, reduction, or modification of health-care facilities or services.

630 l. Other factors that the Department may determine are pertinent to health-care facility utilization.

631 (4) The Department shall publish the study on its website and submit copies of the study to the Governor, the
632 General Assembly, and the Director and the Librarian of the Division of Legislative Services.

633 (5) The Executive Director and Advisory Board shall use the study as a resource in the review of each
634 application under this chapter.

635 Section 13. This Act takes effect 6 months after [the date of enactment of this Act].

636 Section 14. The first report under § 9312, Title 16 of this Act is due no later than [the second January 1 after
637 the date of enactment of this Act].

638 Section 15. This Act applies to an application that is filed on or after [the effective date of this Act].

639 Section 16. Advisory Board membership under § 9303, Title 16 of this Act take effect on [the effective date of
640 this Act].

SYNOPSIS

This Act is a result of the Joint Legislative Oversight and Sunset Committee's ("JLOSC") review of the Delaware Health Resources Board, which this Act renames the Delaware Health Resources Advisory Board ("Advisory Board"). Based on the research, review, and discussion of both the JLOSC and a task force created to assist the JLOSC's research, JLOSC approved recommendations to change the Advisory Board into an advisory council and move the Advisory Board's decision-making authority to the Delaware Health Care Commission's executive director. In addition to those approved recommendations, this Act also implements JLOSC's approval to amend the Advisory Board's statute in the following ways:

- Renames the certificate of public review process to the nationally-recognized name of "certificate of need."
- Clarifies procedures and review considerations, including removing the Health Resources Management Plan ("Plan") and codifying relevant sections of the Plan. The Plan will be replaced by a statewide health-care facility utilization study, be conducted on a biennial basis, and include utilization information to process certificate of review applications.
- Adjusting for inflation, updates the monetary threshold that triggers the requirement for a certificate of need application. The monetary threshold has not been updated since 2007.
- Removes references to the Bureau of Health Planning and Resources Management, because staff support was transferred in 2012 to the Delaware Health Care Commission and DHSS, Office of the Secretary.

This Act takes effect 6 months after the date of enactment. This Act does not apply to applications that are submitted before the enactment date of this Act.