§ 9301. Purpose: Health Planning and Resources Management

It is the purpose of this chapter to assure that there is continuing public scrutiny of certain health-care developments which could negatively affect the quality of health care or threaten the ability of health-care facilities to provide services to the medically indigent. This public scrutiny is to be focused on balancing concerns for cost, access and quality.

§ 9302. Definitions: Health Planning and Resources Management

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

(1) "Board" shall mean the Delaware Health Resources Board established pursuant to § 9303 of this title.

(2) "Bureau" shall mean the Bureau of Health Planning and Resources Management within the Department of Health and Social Services.

(3) "Certificate of Public Review" shall mean the written approval of an application to undertake an activity subject to review as described in § 9304 of this title.

(4) "Health-care facility" shall include hospital, nursing home, freestanding birthing center, freestanding surgical center, freestanding acute inpatient rehabilitation hospital, and freestanding emergency center, whether or not licensed or required to be licensed by the State, whether operated for profit or nonprofit and whether privately owned or operated or owned or operated by a unit of State or local government. The term also includes continual care communities and any other nontraditional, long-term care facilities identified by the Department of Health and Social Services or the Delaware Health Care Commission. The term does not include Christian Science sanatoriums operated or listed and certified by the First Church of Christ Scientist, Boston, Massachusetts. The term shall not include any physician's office, whether an individual or group practice, any independent clinical laboratory or any radiology laboratory. The term shall also not include the office of any other licensed health-care provider, including, but not limited to, physical therapist, dentist, physician assistant, podiatrist, chiropractor, an independently practicing nurse or nurse practitioner, optometrist, pharmacist or psychologist. The term also shall not include any dispensary or first aid station located within a business or industrial establishment maintained solely for the use of employees, provided that the facility does not contain inpatient beds, nor shall it apply to any 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 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) "Health services" shall mean clinically related (i.e., diagnostic, curative or rehabilitative) services provided in or through health-care facilities.

(6) "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.

(7) "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.
§ 9303. Delaware Health Resources Board: Health Planning and Resources Management

(a) There is hereby established a Delaware Health Resources Board to foster the cost-effective and efficient use of health-care resources and the availability of and access to high quality and appropriate health-care services.

(b) 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.

(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.

(d) The duties and responsibilities of the Board shall include, but not be limited to, 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.
THE DATABASE OF STATE LAWS IMPACTING HEALTHCARE COST AND QUALITY

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;

(2) Review Certificate of Public Review applications filed pursuant to this chapter and make decisions on same. Decisions shall reflect the importance of assuring that health-care developments do not negatively affect the quality of health care or threaten the ability of health-care facilities to provide services to the medically indigent. Decisions can be conditional but the conditions must be related to the specific project in question;

(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;

(4) Address specific health-care issues as requested by the Governor or the General Assembly;

(5) Adopt bylaws as necessary for conducting its affairs. Board members shall 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

(6) Coordinate activities with the Delaware Health Care Commission, the Department of Health and Social Services and other groups as appropriate.

(e) The Governor may at any time, after notice and hearing, remove any board member for gross inefficiency, neglect of duty, malfeasance, misfeasance or nonfeasance in office. A member shall be deemed in neglect of duty if they are absent from 3 consecutive board meetings without good cause or if they attend less than 50% of board meetings in a calendar year.

§ 9304. Activities subject to review [Effective until Dec. 31, 2020]: Health Planning and Resources Management

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

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

(2) Any expenditure by or on behalf of a health-care facility in excess of $5.8 million, 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, is a capital expenditure. A capital expenditure for purposes of constructing, developing or otherwise establishing a
medical office building shall not be subject to review under this chapter. 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 acquisition shall be deemed a capital expenditure subject to review. The Board may exempt from review capital expenditures when determined to be necessary for maintaining the physical structure of a facility and not related to direct patient care. 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 capital expenditures from review;

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

(5) [Expired].

(b) Notwithstanding any other provision in this chapter to the contrary, any person who held, as of November 9, 2015, a certificate of public review issued by the Board authorizing the construction of a 90-bed psychiatric hospital in Georgetown, Delaware, regardless of the certificate’s date of expiration or whether the certificate has otherwise been challenged on appeal or is otherwise subject to legal challenge, shall not be required to obtain any additional certificate of public review under this chapter prior to the construction, development, or other establishment of the psychiatric hospital. Any psychiatric hospital constructed, developed, or established under this subsection shall not have any license or authority to operate denied, revoked, or restricted on the grounds that a certificate of public review has not been obtained or has otherwise been challenged on appeal or is otherwise subject to legal challenge.

§ 9304. Activities subject to review [Effective Dec. 31, 2020]: Health Planning and Resources Management

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

(1) The construction, development or other establishment of a health-care facility or the acquisition of a nonprofit health-care facility;
(2) Any expenditure by or on behalf of a health-care facility in excess of $5.8 million, 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, is a capital expenditure. A capital expenditure for purposes of constructing, developing or otherwise establishing a medical office building shall not be subject to review under this chapter. 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 acquisition shall be deemed a capital expenditure subject to review. The Board may exempt from review capital expenditures when determined to be necessary for maintaining the physical structure of a facility and not related to direct patient care. 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 capital expenditures from review;

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

(5) [Expired].

(b) [Expired].

§ 9305. Procedures for review: Health Planning and Resources Management

Reviews under this chapter shall be conducted in accordance with the following procedures:

(1) Notices of intent. — At least 30 days but not more than 180 days prior to submitting an application for review under this chapter, applicants shall submit to the Bureau a notice of intent in such form as may be determined by the Board to cover the scope and nature of the project. An application may be submitted less than 30 days from submitting the notice of intent only with the written approval of the Board. A notice of intent expires and is rendered invalid if no subsequent application for review is submitted to the Board within 180 days following the date on which the notice of intent is submitted.

(2) Applications for review. — Application forms will be developed by the Board and may vary according to the nature of the application.
(3) Deadlines and time limitations. — Upon receipt of an application under this chapter, the Bureau shall have 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. The same steps shall be taken as with the initial submission each time that additional information is required.

Except as provided below, the review of an application shall take no longer than 90 days from the date of notification as covered under paragraph (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), the Board may extend the maximum review period up to 180 days from the date of notification. Such extensions shall be invoked only as necessary to allow the development of appropriate review criteria or other guidance when these are 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.

In the case of a project required to remedy an emergency situation which threatens the safety of patients or the ability of the health facility to remain in operation, an abbreviated application shall be submitted in such format as the Board prescribes. As quickly as possible, but within 72 hours after receipt, the Board shall render a decision as to whether or not the project shall be treated as an emergency and whether or not the application shall be 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 review; notification. — Within 5 working days of determining that an application under this chapter is complete, the Bureau 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. A notice shall also appear in a newspaper of general circulation which shall serve as written notification to the general public. The date of notification is the date on which such notice appears in the newspaper. The notification shall identify the applicant, indicate the nature of the application, specify the period during which a public hearing in the course of the review as covered in paragraph (6) of this section may be requested, and indicate the manner in which notice will be provided of the time and place of any hearing so requested.

(5) Findings. — Upon completion of a review under this chapter, and within the time frames outlined in paragraph (3) of this section, the Bureau shall notify in writing the applicant and anyone else upon request as to the Board’s decision, including the basis on which the decision was made. Decisions can be conditional, but the conditions must be related to the specific project in question.

(6) Public hearing in the course of review. — Within 10 days after the date of notification as described in paragraph (4) of this section, a public hearing in the course of review may be requested in writing by any person. The Board shall provide for a public hearing if requested and shall provide 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.

(7) Administrative reconsideration — Procedure for Board. — Any person may, for a good cause shown, request in writing a public hearing for purposes of reconsideration of a Board decision rendered under paragraph (5) of this section. The Board may not impose fees for such a hearing. 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. Presents newly discovered, significant, relevant information not previously available or considered by the Board; and

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

c. Demonstrates that the Board has materially failed to follow its adopted procedures in reaching its decision.

A request for such a hearing must be received within 10 days of the decision. The hearing shall commence within 45 days of the request.

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

(8) Appeal — Applicant. — A decision of the Board following review of an application pursuant to paragraph (5) of this section, an administrative reconsideration pursuant to paragraph (7) of this section, or the denial of a request for extension of a Certificate of Public Review pursuant to § 9307 of this title, may be appealed within 30 days to the Superior Court. Such appeal shall be on the record.

(9) Access by public. — The general public shall be provided access to all applications reviewed under this chapter and to all other written materials pertinent to any review of an application.

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

Filing fees shall be determined from the following table:

<table>
<thead>
<tr>
<th>Capital Expenditures</th>
<th>Filing Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than $500,000</td>
<td>$100</td>
</tr>
<tr>
<td>$500,000 to $999,999</td>
<td>$750</td>
</tr>
<tr>
<td>$1,000,000 to $4,999,999</td>
<td>$3,000</td>
</tr>
<tr>
<td>$5,000,000 to $9,999,999</td>
<td>$7,500</td>
</tr>
<tr>
<td>$10,000,000 and over</td>
<td>$10,000</td>
</tr>
</tbody>
</table>
Filing fees shall be due 30 days after the date of notification of the beginning of review as covered under paragraph (4) of this section. This due date may be extended up to 10 additional days at the discretion of the Bureau. Applications for which filing fees have not been paid within this time frame shall be considered to be withdrawn. All filing fees shall be deposited in the General Fund.

§ 9306. Review considerations: Health Planning and Resources Management

In conducting reviews under this chapter, the Board shall consider as appropriate at least 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;

(2) The need of the population for the proposed project;

(3) The availability of less costly and/or more effective alternatives to the proposal, including alternatives involving the use of resources located outside the State;

(4) The relationship of the proposal to the existing health-care delivery system;

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

(6) The anticipated effect of the proposal on the costs of and charges for health care; and

(7) The anticipated effect of the proposal on the quality of health care.

§ 9307. Period of effectiveness of Certificate of Public Review: Health Planning and Resources Management

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

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

§ 9308. Sanctions: Health Planning and Resources Management

(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.

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

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

§ 9309. Surrender, revocation and transfer of Certificate of Public Review: Health Planning and Resources Management

(a) 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.

(b) 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. Prior to revoking a Certificate of Public Review, the Board shall provide written notice to the holder of the certificate stating its 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. No Certificate of Public Review shall be revoked by the Board without first providing the holder of the certificate an opportunity for a hearing. The Board’s decision to revoke a Certificate of Public Review may be appealed pursuant to § 9305(8) of this title.

(c) 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.

§ 9310. Immunity: Health Planning and Resources Management

No member, officer or employee of the Board, the Bureau or health care facility shall be subject to, and such persons shall be immune from, any claim, suit, liability, damages or any other recourse, civil or criminal, arising from any act or proceeding, decision or determination undertaken or performed, or recommendations made while discharging any duty or authority under this chapter, so long as such person acted in good faith, without malice, and within the scope of such person’s duty or authority under this chapter or any other provisions of the Delaware law, federal law or regulations or duly adopted rules and regulations providing for the administration of this chapter, good faith being presumed until proven otherwise, with malice to be shown by the complainant.
§ 9311. Charity care: Health Planning and Resources Management

Any person subject to a CPR review pursuant to this chapter shall perform and accept within this State charity care to the extent required by the Board to those individuals who meet the criteria for rendering charity care established by the Board, and shall continue to provide charity care in each fiscal year as determined by the Board. The authority to enforce charity care requirements shall rest with the Department of Health and Social Services.

§ 9312. Charity care: Health Planning and Resources Management

Transferred to § 9311 of this title by 77 Del. Laws, c. 132, § 2, effective July 8, 2009.